THE
2017-18

# Medical-Dental-Legal UPDATE

***Medical Malpractice • Risk Management • Practice Management***
***Healthcare Law • Selected Clinical Topics***

This Syllabus was issued to

_____
(Name)

By: Classroom Facilitator _____
(Name)

On _____ (Date) in _____ (City), _____ (State)


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# Medical-Dental-Legal UPDATE

## COURSE OBJECTIVES

After completing ***The 2017-18 Medical-Dental-Legal Update*** you should have acquired the knowledge that will better enable you to:

- Recommend **preventive lifestyle behaviors and protective pharmacotherapy**.
- Assess the appropriateness of the **direct patient care** model for your practice.
- Utilize a variety of clinically **relevant but relatively unknown treatments**.
- Better recognize and respond to victims of **child violence**.
- Better understand and deal with **medical malpractice** litigation.
- More effectively **reduce practice risk and protect assets** exposed to it.
- More effectively protect your practice against **fraud and embezzlement**.
- Better diagnose and treat **odontogenic infections**.
- Identify **newly FDA approved drugs, CDC immunization updates, and drug safety guidelines**.
- Better manage **Type 2 Diabetes** in older adults.
- More effectively communicate with **unreasonable patients**.
- Better interpret **liver function tests**.
- Utilize **non-pharmacologic pain management** techniques.
- Evaluate and improve your practice's **revenue cycle**.
- Better identify and treat **neurologic emergencies**.
- More effectively **engage patients** in their own care.

All learning objectives above address IOM/ACGME core competencies.

THE 2017-18

# Medical-Dental-Legal UPDATE

## FACULTY DISCLOSURES

The individuals listed below have control over the content of ***The 2017-18 Medical-Dental-Legal Update***. None of them have a financial relationship with a commercial interest whose products or services are discussed in the presentation(s) over which they have control:

**David R. Victor, Esq.**, president, American Educational Institute; course director, *The 2017-18 Medical-Dental-Legal Update*
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The following faculty members of ***The 2017-18 Medical-Dental-Legal Update*** have a financial relationship with a commercial interest whose products or services are discussed in their presentation:

**Louis Kuritzky, MD**, consultant for Boehringer Ingleheim, Sanofi, Novo Nordisk, and Eli Lilly and Company

# FACULTY

## Louis Kuritzky, MD

Louis Kuritzky, MD, of Gainesville, Florida, is a board-certified, family practitioner. He is a clinical assistant professor emeritus in the University of Florida's Department of Family Medicine where he has twice received the Family Practice Residency's *Teacher of the Year Award*.

Dr. Kuritzky has given over 1,000 presentations to medical audiences on dozens of clinical topics and has authored over 150 articles in journals including *New England Journal of Medicine, JAMA, Comprehensive Therapy, Hospital Practice, Consultant, Postgraduate Medicine, Journal of Pain and Palliative Care,* and *Patient Care*. He is a consultant for Boehringer Ingelheim, Sanofi, Novo Nordisk and Eli Lilly and Company.

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# "Things I Wish I Knew Last Year"

## What to do about this facial flushing

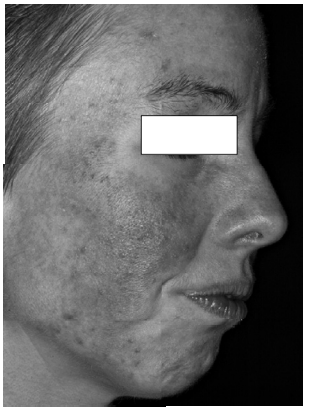
A 36 y.o. has failed multiple treatments to reduce facial flushing attributed to rosacea. She is frustrated that people keep inquiring about excessive alcohol intake, since she does not drink. She has failed multiple 'traditional' treatments. What might help?

a) Niacin (as nicotinic acid) 2 g daily p.o.

b) Nifedipine 60 mg po

c) She should stop lying about being a non-drinker & sober-up

d) Carvedilol



Habif TP Clinical Dermatology (6th Edition) 2016 Elsevier

*Pronounced facial flushing and persistent erythema of rosacea effectively treated by carvedilol, a nonselective β-adrenergic blocker*

*Chia-Chi Hsu, MD, Julia Yu-Yun Lee, MD*

*Journal of the American Academy of Dermatology*
Volume 67, Issue 3, Pages 491-493 (September 2012)
DOI: 10.1016/j.jaad.2012.04.017

## **E**rythemato**t**elangiectatic **R**osacea Endorsed Treatments

Severe Erthyematotelangiectatic Rosacea

- B-Blockers
- Clonidine
- Naloxone
- Ondansetron
- Endoscopic Thoracic Sympathectomy

HSU CC, Lee JYY J Am Acad Dermatol 2012;67(3):491-492

## ETR: Carvedilol Case Series

- Study: ETR Case series (n= 11)
- Based upon initial success in 1 case
- Previous Failed Rx with ≥1 of
  - Doxycycline
  - Corticosteroids
  - Propranolol
  - Clonidine
  - Metronidazole
  - Ondansetron
  - Tacrolimus/pimecrolimus
  - Thoracic sympathectomy
  - Stellate ganglion block
  - Pulsed dye laser

HSU CC, Lee JYY J Am Acad Dermatol 2012;67(3):491-492

## ETR: Carvedilol Case Series

- Rx: carvedilol 3.125 mg/d → 31.25 mg/d divided b.i.d.-t.i.d. added to existing Rx x 1 yr
- Metrics:
  - Photo-based facial erythema
  - Cheek temperature
  - VAS 0-10 (pt assessment)

HSU CC, Lee JYY J Am Acad Dermatol 2012;67(3):491-492

## ETR: Carvedilol Case Series Results

"All patients experienced significant clinical improvement within 3 weeks (range 3-21 days, mean 10.5 days)."

HSU CC, Lee JYY J Am Acad Dermatol 2012;67(3):491-492

## ETR: Carvedilol Case Series Results

| | Carvedilol |
|---|---|
| Cheek Temperature | ↓2.2$^0$ C |
| VAS: Baseline<br>VAS End of Rx | 8.4/10<br>2.1/10 |
| | *all results are MEAN |

HSU CC, Lee JYY J Am Acad Dermatol 2012;67(3):491-492

## ETR: Carvedilol Case Series Discussion

"Carvedilol appears special among β-blockers in its significant antioxidant and anti-inflammatory properties, which may explain its efficacy in treating ETR in the current study."

HSU CC, Lee JYY J Am Acad Dermatol 2012;67(3):491-492

## Osteoporosis Risk Stratification: MEN

A 62 y.o. uninsured MAN weighs 180# and does not have COPD. His 72 y.o. brother, who has COPD, just sustained an osteoporotic hip fracture. He would like to avoid the expense of a DEXA Scan. Based on this information alone, what is the likelihood that a DEXA scan will show osteoporosis?

a) <2%

b) 10%

c) 25%

d) >50%

## OSPS in Men: Foundations

- Men uncommonly screened, even
  - on chronic steroids
  - after fragility Fx
- #3 rank for hospital days in men
- Male mortality > female for
  - In-hospital post-Fx mortality
  - 1-yr post-Fx mortality
- USPSTF 2011 Male OSPS Statement: "I"

Cass AR, Shepherd AJ J Am Board Fam Med 2013;26:436-444

## MORES Score

| Risk Factor | Points |
|---|---|
| Age (years) | |
| ≤55 | 0 |
| 56-74 | 1 |
| ≥75 | 2 |
| Weight (kg) | |
| ≤70 | 6 |
| 71-80 | 4 |
| >80 | 0 |
| COPD | 3 |

+ Screen: ≥6 points

Cass AR, Shepherd AJ J Am Board Fam Med 2013;26:436-444

## MORES Score Validation Trial

- Study: Men age ≥ 60 yrs attending Primary Care clinic for 'usual care'
- Exclusions
  - Hx of OSPS or bone disease (e.g., Pagets)
  - On any OSPS Rx for any indication
  - Bilateral Hip replacement surgery
  - Weight >300# (DEXA scanner limit)
- Metric: DEXA after MORES Score
- Outcome: MORES Sensitivity & Specificity

Cass AR, Shepherd AJ J Am Board Fam Med 2013;26:436-444

## MORES Score Validation Trial Results

"Men who screened negative with the MORES had only a 1% chance of having osteoporosis."

Cass AR, Shepherd AJ J Am Board Fam Med 2013;26:436-444

## A Young Woman with Moderate-Severe Depression

Tiffany is a 32 year old woman with moderate-severe depression (Hamilton Depression Rating Scale score = 24). She wants to know if there are any non-drug Rxs that are effective for depression. Your evidence-based YES answer includes:

a) Systemic Vitamin D

b) Exercise

c) Omega 3 Fatty Acids

d) Steam-bath therapy

## Exercise & Depression: Premises

- Exercise ↓ incidence mood/anxiety disorders
- MDD: Efficacy of exercise as
  - monotherapy: YES
  - augmentation Rx: YES
- May also benefit insomnia, cognitive Fx
- Doesn't work for everyone

Suterwala AM et al J Clin Psych 2016;77(8):1036-1042

**Affect Following First Exercise Session as a Predictor of Treatment Response in Depression**

Anisha M. Suterwala BA, Chad D Rethorst , PhD, Thomas J Carmody PhD, Tracy I Greer, PhD, Bruce D Grannemann, MA, Manish Jha, MD, and Madhukar H Trivedi, MD

**J Clin Psychiatry 2016;77(8):1036-1042**

## Response to 1st Exercise Session Predicts Success in Depression

- Study: RCT MDD (N=122)
- Inclusion
  - Age 18-70
  - Nonpsychotic MDD as per DSM-IV
  - ≥ 6 weeks adequate dose SSRI
  - Moderate residual Sx (HDR-S≥ 14)
  - Not already engaged in regular exercise

Suterwala AM et al J Clin Psychiatry 2016;77(8):1036-1042

## Response to 1st Exercise Session Predicts Success in Depression

- Rx: Moderate-vigorous exercise X 12 weeks
  - 'Public Health' dose: 180 mins/week
  - 'Low' dose: 45 mins/wk
- Metric: PANAS (Positive and Negative Affect Scale) after 1st session
- Outcome: Relationship between PANAS on Day 1 and end-of-trial depression status

Suterwala AM et al J Clin Psychiatry 2016;77(8):1036-1042

## Response to 1st Exercise Session Predicts Success in Depression

### Results

"The PANAS composite affect score predicted change in IDS-C score as well as Rx response and remission for those in the high-dose group but not in the low-dose group."

Suterwala AM et al J Clin Psychiatry 2016;77(8):1036-1042

## Response to 1st Exercise Session Predicts Success in Depression

### Conclusions

"These findings suggest that the composite positive affect following the first exercise session has clinical utility to predict Rx response to exercise in depression and match the 'right patient'; with the 'right Rx'."

Suterwala AM et al J Clin Psychiatry 2016;77(8):1036-1042

## Ginko Biloba for Cognitive Edge

A 64 y.o. woman with T2 DM stopped her glimepiride 2 months ago because of her limited income. She takes a variety of supplements, e.g., multivitamins, omega-3 fatty acids, and ginko biloba, which she maintains 'has been proven to maintain mental sharpness'. Your evidence-based response

a) Gingko is a good investment of her $$; KOKO

b) Omega-3-FA enhance the + effects of gingko

c) A large RCT did *not* confirm + gingko effects for cognition

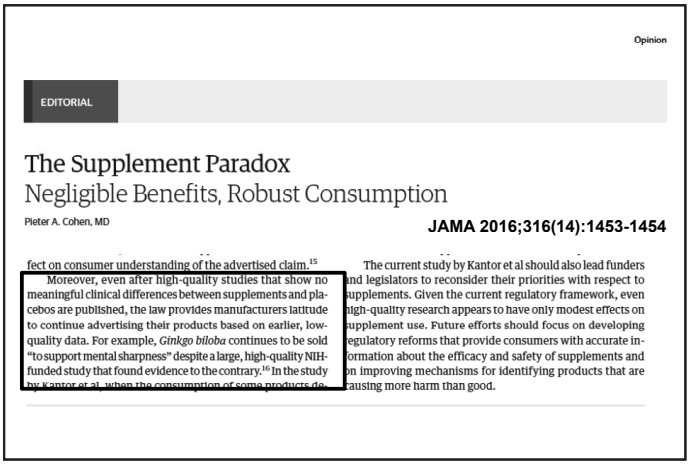
d) Favorable cognitive effects have only been seen in persons over age 75

## Supplements: Majority Rules?

Interviews with NHANES Adults (n = 37, 958)

"Overall, the use of supplements remained stable between 1999-2012, with 52% of US adults reporting use of any supplements in 2011-2012."

Kantor ED et al JAMA 2016;316(14):1464-1474



Opinion

EDITORIAL

The Supplement Paradox

Negligible Benefits, Robust Consumption

Pieter A. Cohen, MD

JAMA 2016;316(14):1453-1454

fect on consumer understanding of the advertised claim.[15]

Moreover, even after high-quality studies that show no meaningful clinical differences between supplements and placebos are published, the law provides manufacturers latitude to continue advertising their products based on earlier, low-quality data. For example, *Ginkgo biloba* continues to be sold "to support mental sharpness" despite a large, high-quality NIH-funded study that found evidence to the contrary.[16] In the study by Kantor et al, when the consumption of some products de-

The current study by Kantor et al should also lead funders and legislators to reconsider their priorities with respect to supplements. Given the current regulatory framework, even high-quality research appears to have only modest effects on supplement use. Future efforts should focus on developing regulatory reforms that provide consumers with accurate information about the efficacy and safety of supplements and on improving mechanisms for identifying products that are causing more harm than good.

## What Paradox?

"… a steady stream of high-quality studies evaluating dietary supplements has yielded predominantly disappointing results about potential health benefits, whereas evidence of harm has continued to accumulate."

Cohen PA JAMA 2016;316(14):1453-1454

## Are You Prepared?

"Moreover, even *after** high-quality studies that show no meaningful clinical differences between supplements and placebos are published, the law provides manufacturers latitude to continue advertising their products based on earlier, low quality data."

*emphasis added

Cohen PA JAMA 2016;316(14):1453-1454

ACS Surgery News

FROM THE JOURNALS

**Herbal/dietary supplements linked to liver injury requiring transplant**

**Publish date:** March 1, 2017

**By:** Bianca Nogrady, Frontline Medical News

## Risks of Herbal/Dietary Supplements

"Herbal or Dietary supplements are the fourth most common cause of drug-induced acute hepatic necrosis requiring liver transplantation in the U.S.…."

Nogrady B Family Practice News 2017 (March 15):p 5

## Risks of Herbal/Dietary Supplements

- Study: urgent liver transplant registry data
- Population: Adults(n =2,408) mean age 36.8
  - Drug induced = 625
- mean Herbal or dietary Supplements = 21
- Example agents cited: Lipolyze, Hydroxcut, OxyElite Pro

Nogrady B Family Practice News 2017 (March 15):p 5

## Risks May Be an Underestimate

"The authors suggested the true figure for herbal/dietary supplement-induced liver transplantation may be underestimated, pointing to the fact that in this study a further 154 cases were recorded as drug-induced injury, but no drug was listed."

Nogrady B Family Practice News 2017 (March 15):p 5

## Starting A Combined Oral Contraceptive

Your Monday morning patient, Martina is a 19 yo woman who has elected to begin a combined oral contraceptive (e.g., Ortho-Novum 1/35). Her last menstrual period ended 10 days ago. When/how should she start her pills?

a) This upcoming Sunday

b) The first Sunday after her next menses begins

c) Today

d) On the first day of her next menses

## Immediate vs 'Conventional' OC Initiation

"The conventional approach to initiating OCs is to start during the menstrual period."

Rationale

- Patient not pregnant
- Ovulation inhibited from 1st cycle
- Minimizes disruption of bleeding pattern

Westoff C, et al Fertility Sterility 2003;79(2):322-329

## Immediate vs 'Conventional' OC Initiation Problems

- Up to 25% of recipients do NOT start after waiting till next menses. WHY?
  - Pregnancy
  - Changes in motivation
  - Confusion on when/how to start
  - Forgetting
  - Fear of side effects

Westoff C, et al Fertility Sterility 2003;79(2):322-329

## "Quick Start" Method for OC Initiation

- Woman takes first pill observed in clinic
- Continues at home
- Condom back-up contraception X 7 days

But does this method result in more irregular bleeding, reportedly the most common reason for OC discontinuation?

Westoff C, et al Fertility Sterility 2003;79(2):322-329

## "Quick Start" OC Initiation: A Clinical Trial

- RCT: adult women age 18-35 (n=113)
- Inclusion
  - Regular menses X 12 months
  - No recent use of hormonal contraception
  - If previously pregnant, >2 menses post-partum
  - No EC in current menstrual cycle
  - Negative pregnancy test
- Exclusion: unprotected sex in prior 10 days

Westoff C, et al Fertility Sterility 2003;79(2):322-329

## "Quick Start" OC Initiation: A Clinical Trial

- Method: QS vs CS X 90 days
- Rx: 35 mcg ethinyl estradiol combination OC pill
- Bleeding pattern monitored by diary
- Outcomes:
  - Patient satisfaction
  - Bleeding Patterns

Westoff C, et al Fertility Sterility 2003;79(2):322-329

## "Quick Start" OC Initiation: A Clinical Trial

| All results over a 90-day interval | Quick Start | Conventional Start | P value |
|---|---|---|---|
| # spotting days | 8.6 | 10.1 | NS |
| >4 spotting episodes | 20.6% | 26.8% | NS |
| Prolonged bleeding | 22.2% | 24.4% | NS |
| Amenorrhea | 0% | 0% | NS |
| Bleeding Pattern Acceptable | 46% | 43.9% | NS |
| Same Start Next Time | 92.1% | 95.1% | NS |

Westoff C, et al Fertility Sterility 2003;79(2):322-329

## QS vs CS: Concerns?

"One concern regarding the QS approach is that if fertilization has [already] occurred… early pregnancy will be exposed to contraceptive hormones. In 40 years' experience…many women have inadvertently taken OCs during early pregnancy, and substantial evidence exists that this exposure is not associated with adverse pregnancy outcomes."

Westoff C, et al Fertility Sterility 2003;79(2):322-329

## QS vs CS: Aside

Drop outs?

"One subject in each group was found to be pregnant during f/u despite a - pregnancy test at enrollment. The CS subject became pregnant while waiting to start OCs; the QS subject was found to be pregnant after she completed taking her first cycle of pills, and then disclosed that she had an episode of unprotected intercourse immediately before enrollment, which she had not previously reported."

Westoff C, et al Fertility Sterility 2003;79(2):322-329

## EARS?

Which of the following is true about this gent?

a) He is probably a better than average listener

b) He is probably a long-term, high-volume Wax Museum donor

c) He has a family history of progeria

d) He has increased probability of CAD

**Relation of Diagonal Ear Lobe Crease to the Presence, Extent, and Severity of Coronary Artery Disease Determined by Coronary Computed Tomography Angiography**

Haim Shmilovich, MD[a,*], Victor Y. Cheng, MD[b], Ronak Rajani, MD[a], Damini Dey, PhD[b], Balaji K. Tamarappoo, MD, PhD[a], Ryo Nakazato, MD, PhD[a], Thomas W. Smith, MD[a], Yuka Otaki, MD, PhD[a], Rine Nakanishi, MD, PhD[a], Heidi Gransar, MS[a], William Paz, RT[a], Raymond T. Pimentel, RT[a], Sean W. Hayes, MD[b], John D. Friedman, MD[b], Louise E.J. Thomson, MBChB[b], and Daniel S. Berman, MD[b]

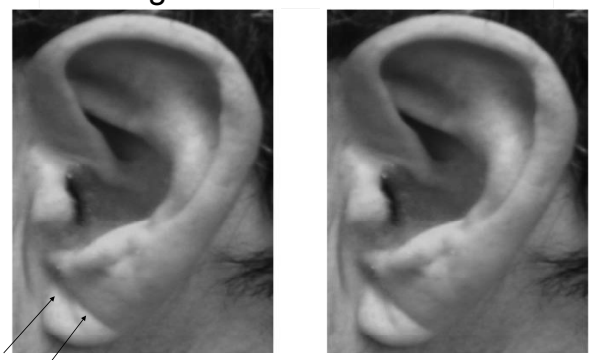
Am J Cardiol 2012;109:1283-1287

## Frank's Sign

"Diagonal ear lobe crease (DELC)…is a wrinkle-like line extending diagonally from the tragus across the lobule to the rear edge of the auricle of the ear….first associated with CAD…by Frank published in 1973."

Shmilovich H, et al Am J Cardiol 2012;109:1283-1287

## Diagonal Ear Lobe Crease



Shmilovich H, et al Am J Cardiol 2012;109:1283-1287

## Frank's Sign: Valid?

"Controversy exists concerning the relation between diagonal ear lobe crease and CAD"

Shmilovich H, et al Am J Cardiol 2012;109:1283-1287

## Frank's Sign: Valid?

- Study: aSx Adults with no Hx CAD (n=430)
- Metric: Coronary CT Angiography
- Endpoints:
  - Any CAD
  - Significant CAD (≥50% stenosis)
  - Multivessel disease
  - # segments with plaque

Shmilovich H, et al Am J Cardiol 2012;109:1283-1287

## Frank's Sign: Outcome

"After adjusting for confounders, DELC remained a significant predictor of all 4 measurements of CAD (Odds Ratio 1.8-3.3, p 0.002-0.017)."

Shmilovich H, et al Am J Cardiol 2012;109:1283-1287

## Frank's Sign: Conclusion

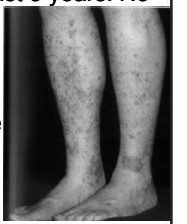
"In conclusion, in this study of patients imaged with CT angiography, finding DELC was independently and significantly associated with ↑ prevalence, extent, and severity of CAD."

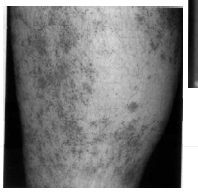
Shmilovich H, et al Am J Cardiol 2012;109:1283-1287

## Asymptomatic Rust-Colored Spots

A 48 y.o. man seeks advice about asymptomatic spots on both lower legs, gradually progressive for at least 5 years. No other health problems or medications. This is

a) Uniformly fatal guttate melanosis.
b) Schamberg's Disease
c) Lamivudine toxicity from adulterated cocaine
d) Venous insufficiency





## Asymptomatic Rust-Colored Spots

A 48 y.o. man seeks advice about asymptomatic spots on both lower legs, present for at least 5 years. No other health problems or medications. This is

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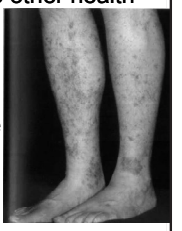
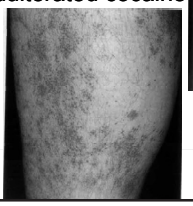




## Schamberg's Disease

- AKA: Progressive pigmented purpuric dermatosis, Purpura Simplex
- Males > Females
- Cause Unknown
- Characteristic feature: "orange-brown, pinhead-sized 'cayenne pepper' spots."
- "Lesions persist, but 67% eventually clear."

Habif T Clinical Dermatology 6th Edition Elsevier 2016

Successful treatment of Schamberg's disease with pentoxifylline

Yoko Kano, MD, Kashiko Hirayama, MD, Midori Orihara, MD, and Tetsuo Shiohara, MD
*Tokyo, Japan*

J Am Acad Dermatol 1997;36:827-830

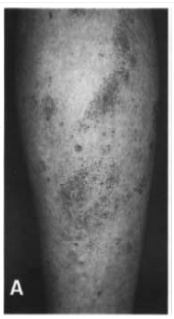
## Schamberg's Disease: Pentoxifylline

- Study: Schamberg's disease patients (n=3)
- Rx: pentoxifylline 300 mg t.i.d. x 8 weeks
- Site: Tokyo, Japan
- Outcome: all 3 improved; 1 recurrence responded to re-Rx

Kano Y, et al J Am Acad Dermatol 1997;36:827-830

## Schamberg's: Pentoxifylline Rx x 8 weeks

Before





After

Kano Y, et al J Am Acad Dermatol 1997;36:827-830

## Schamberg's Disease: Pentoxifylline

- Study: Schambergs Disease patients (n=30)
- Rx: pentoxifylline 400 mg t.i.d. X 9 weeks

| | Mild | Moderate | Marked |
|---|---|---|---|
| Improvement | 4 (13.3%) | 5 (16.6% | 17 (56.6%) |
| "Improvement was seen in 26 (86.6%) of patients." | | | |

- "We conclude that pentoxifylline should be considered as 1st line therapy in all patients with Schamberg's disease."

Majid RM J Pakistan Assoc Dermatologists 2008;18:97-99

## What's Causing the Hypomagnesemia

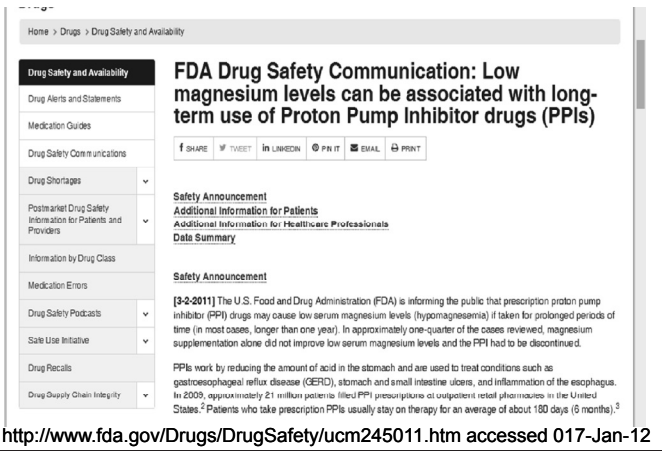
A 32 y.o. woman who presented to the emergency room with extreme fatigue and weakness. Her plasma magnesium level is 1.2 mg/dL (normal range = 1.7 mg/dL – 2.3 mg/dL). Which agent below could have caused this?

a) Daliresp (Roflumilast)

b) Spironolactone (Aldactone)

c) Omeprazole (Prilosec)

d) Amiloride (Midamor)




http://www.fda.gov/Drugs/DrugSafety/ucm245011.htm accessed 017-Jan-12

## PPIs and Hypomagnesemia

"…FDA is informing the public that prescription proton pump inhibitor drugs may cause …hypomagnesemia if taken for prolonged periods of time (in most cases, longer than one year)."

http://www.fda.gov/Drugs/DrugSafety/ucm245011.htm

## PPIs and Hypomagnesemia

- ¼ cases $Mg^{++}$ repletion did not respond
  - Had to D-C PPI
- Pertains to Rx, not OTC

http://www.fda.gov/Drugs/DrugSafety/ucm245011.htm

## PPIs and Hypomagnesemia

"…consider obtaining serum Mg++l levels prior to initiation of prescription PPI Rx in patients expected to be on these drugs for long periods of time, as well as patients who take PPIs with medications such as digoxin, diuretics, or drugs that may cause hypomagnesemia."

http://www.fda.gov/Drugs/DrugSafety/ucm245011.htm

o

## PPIs and Hypomagnesemia: MOA

"The mechanism responsible for hypomagnesemia associated with long term PPI use is unknown."

http://www.fda.gov/Drugs/DrugSafety/ucm245011.htm

PPI/Hypomagnesemia Data Set (n = 61)

- Patients on diuretics excluded UNLESS
  - D-C diuretic → no Δ $Mg^{++}$
  - PPI D-C → ↑ $Mg^{++}$
- Duration of PPI Rx to produce ↓ $Mg^{++}$
  - ≥3 months, typically, > 1 year
- post-PPI $Mg^{++}$ normalization time = 7 d (mean)
- Re-challenge → hypomag at 14 d (mean)

http://www.fda.gov/Drugs/DrugSafety/ucm245011.htm

PPIs and Hypomagnesemia
FDA Example (Real) Cases

- 63 y.o. ♀ , 67 y.o. ♂
- PPI Rx duration 6 yrs (♀), 11 years (♂)
- Presentation: Seizures
- IV $Mg^{++}$ could *not* normalize $Mg^{++}$ until PPI was stopped

http://www.fda.gov/Drugs/DrugSafety/ucm245011.htm

SELF EVALUATION

**"Things I Wish I Knew Last Year"**

**1.** A 36 y.o. has failed multiple treatments to reduce facial flushing attributed to rosacea. She is frustrated that people keep inquiring about excessive alcohol intake, since she does not drink. She has failed multiple 'traditional' treatments. What might help?

a. Niacin (as nicotinic acid) 2 g daily p.o.
b. Nifedipine 60 mg po
c. She should stop lying about being a non-drinker & sober-up
d. Carvedilol

**2.** A 62 y.o. uninsured MAN weighs 180# and does not have COPD. His 72 y.o. brother, who has COPD, just sustained an osteoporotic hip fracture. He would like to avoid the expense of a DEXA Scan. Based on this information alone, what is the likelihood that a DEXA scan will show osteoporosis?

a. <2%
b. 10%
c. 25%
d. <50%

**3.** Tiffany is a 32 year old woman with moderate-severe depression (Hamilton Depression Rating Scale score = 24). She wants to know if there are any non-drug Rxs that are effective for depression. Your evidence-based YES answer includes:

a. Systemic Vitamin D
b. Exercise
c. Omega 3 Fatty Acids
d. Steam-bath therapy

SELF EVALUATION

**"Things I Wish I Knew Last Year" cont.**

**4.** A 64 y.o. woman with T2 DM stopped her glimepiride 2 months ago because of her limited income. She takes a variety of supplements, e.g., multivitamins, omega-3 fatty acids, and ginko biloba, which she maintains 'has been proven to maintain mental sharpness'. Your evidence-based response

a. Gingko is a good investment of her $$; KOKO
b. Omega-3-FA enhance the + effects of gingko
c. A large RCT did not confirm + gingko effects for cognition
d. Favorable cognitive effects have only been seen in persons over age 75

**5.** Your Monday morning patient, Martina is a 19 yo woman who has elected to begin a combined oral contraceptive (e.g., Ortho-Novum 1/35). Her last menstrual period ended 10 days ago. When/how should she start her pills?

a. This upcoming Sunday
b. The first Sunday after her next menses begins
c. Today
d. On the first day of her next menses

**6.** Which of the following is true about a patient with a diagonal ear lobe crease?

a. He is probably a better than average listener
b. He is probably a long-term, high-volume Wax Museum donor
c. He has a family history of progeria
d. He has increased probability of CAD

**7.** A 48 y.o. man seeks advice about asymptomatic spots on both lower legs, gradually progressive for at least 5 years. No other health problems or medications. This is

a. Uniformly fatal guttate melanosis.
b. Schamberg's Disease
c. Lamivudine toxicity from adulterated cocaine
d. Venous insufficiency

**8.** A 32 y.o. woman who presented to the emergency room with extreme fatigue and weakness. Her plasma magnesium level is 1.2 mg/dL (normal range = 1.7 mg/dL – 2.3 mg/dL). Which agent below could have caused this?

a. Daliresp (Roflumilast)
b. Spironolactone (Aldactone)
c. Omeprazole (Prilosec)
d. Amiloride (Midamor)

**Answer Key:** 1. D, 2. A, 3. B, 4. C, 5. C, 6. D, 7. B, 8. C

## Ike Z. Devji, Esq.

Ike Z. Devji, Esq., of Phoenix, Arizona, has been solely focused on asset protection and wealth preservation planning for the last 14 years. He and his colleagues have protected over $5 billion in personal assets for a national client base that includes thousands of successful physicians, as well as business owners and entrepreneurs. Mr. Devji is a noted national educator (CME, CLE and CE) and author with over 300 nationally published bylines and a frequent speaker having taught thousands of doctors, lawyers and advisors on asset protection and risk management in addition to being a contributing author to multiple books and a dozen medical journals. He is AVVO rated "10.0 Superb" for seven years in a row and is included in Arizona's Finest Lawyers among other distinctions.

You may contact Mr. Devji with your questions or comments at (602) 808–5540, by email at ID@thewealthy100.com or through his website at www.ProAssetProtection.com.

# Fighting Fraud and Embezzlement in the Medical Practice

By Ike Devji, J.D.

Doctors and practice managers are increasingly exposed to the threat of theft, embezzlement and financial fraud. This risk can be effectively managed with a 3 part strategy that includes:

1. Following financial security best practices, including the simple "trust but verify";
2. Being aware of the most common external ***and*** internal fraud schemes and the red flags they present;
3. Being adequately insured against these losses.

**Procedural Safeguards, a basic checklist of best practices**

- Use **pre-numbered documents** for checks, purchases, sales, shipments, receipts, billings, and collections. Alternately, if your accounting system generates those numbers or prints internally, employees should not be able to alter the numbering process. *When an employee sees that no one is actually looking at the books and doing simple things like comparing receipts, bank deposits, invoices, etc. the opportunity and temptation for abuse is much greater.*
- **Spot checks or random audits** often deter a would-be thief and help create a stop loss event in case fraud or theft is discovered, including one by your CPA that may be limited in time and scope to one specific issue, like deposits, inventory, etc.
- Manage the duties of employees to maintain a **system of checks and balances** and separate those who have custody of assets, record keeping, and authority to conduct financial transactions.
- **Manage HR** for risk and use simple, affordable resources for employee screening and background checks and make sure you are actually calling references. Consider having your executives and employees with significant responsibilities and financial authority fully bonded and insured.
- Consult with your **insurance** expert and see if your business loss coverage does or can include coverage for such losses and for the investigation and

prosecution of such crimes if discovered; nothing's worse than having a crook use your own money to fight you in court.

- If your practice sells or dispenses anything of significant value, **inventory controls** are obviously important as well, but we've seen a variety of property stolen with the help of an employee, from office equipment to office and medical supplies, and even construction materials.
- Consider the use of surveillance cameras in key areas like your checkout/payment desk.

Finally, if you suspect you have such a problem consider your own actions very carefully, don't confront the person directly and certainly don't make these claims to third parties in person or in writing without substantial proof and ideally only after consulting with legal counsel who may involve law enforcement. You may "tip your hand" and allow them to change or destroy evidence or otherwise cover their trail. You are also opening yourself up to substantial legal jeopardy (or worse create a physical danger) for a defamation related claim, another expensive legal issue. Act swiftly and get help and objective analysis no matter how angry you may be and consider what you can do that will quietly end or limit the damage they are doing while you go through the process.

## Invoicing Scams

These scams may be **external** (meaning from a thief completely outside your business) or **internal**, (involving an employee). They often involve some combination of two specific scams; either billing for goods and services never received (fake invoice), or that the victim didn't order (padded or inflated invoice). As with many of the other forms of financial fraud these attempts peak at year-end when scammers know businesses are both busy and working with limited time and that you are often looking for bills to pay before year end for tax reasons. Some scammers even added the traditional, "Pay today for Tax Deduction This Year", message to the bills.

**How Big a Problem is it?**

This form of fraud costs medical practices, businesses, and individuals like you **billions of dollars a year** for goods and services they never get. The scammers are devious and persistent in targeting you, impersonate legitimate vendors and have professional looking paperwork and use scary language that makes you believe you will be subject to fines, penalties, collections, and even legal actions if you don't send them a check. They often send mailings out in large numbers, covering whole states and regions. The biggest ones even have corresponding websites and call centers that will follow up, bill, and collect from your accounting department.

**Potential Signs Of Fraud**

- Duplicate bills and invoice numbers
- P.O. Box return addresses
- Homemade invoices or photocopies without supporting documents
- Invoices from unfamiliar vendors
- Billing from out of state or out of the U.S. for services rendered locally
- Poorly constructed correspondence, invoices and websites with navigation and spelling errors
- Account numbers that are different from your usual ones, even with vendors you actually use
- Lack of verifiable contact info and phone numbers
- Unusual amounts

**What Kind of Things do They Bill For?**

Anything you can imagine, my research showed false invoices for fire extinguisher check-ups, alarm monitoring light bulbs, cleaning, maintenance, fines, and other **recurring expenses** your business would commonly incur. Given the large number of changes in taxes, labor laws, and health-insurance compliance issues for your staff under the Affordable Care Act, criminals are also targeting employers with false employment compliance and violation scare notices.

As one example, a client recently received from a "Labor Standards" organization in the Southwest. The invoice is boldly marked **FINAL NOTICE** in big red letters and says in bold, "Failure to comply with 2013 labor law requirements may lead to government fines and/or audits" and demands a "fee" of $295 and states "NOW DUE." Critical reading reveals that it is not actually bill, but a solicitation that (in my opinion) intentionally crafted to look like a bill for which they'll send you twenty dollars worth of break-room posters that you are not required to buy by law. The state's attorney general issued a warning about this company after the issue came to my attention and this scam is common in every state. The law requires that the "not a bill" disclaimers be as large as the largest typeface used in the letter but they almost never are, so read every bill carefully.

**More than one kind of risk**

Aside from the obvious, paying for something you don't want, need, or never saw, the scammers also now have either a credit card number and all required identifying billing details or your checking account number. While not all of those involved in invoicing scams further misuse that information in other ways, (like printing themselves checks using your bank account and routing number) many do and the first payment may be just the beginning of a long trail of fraud and identity theft. Given the heightened targeting of doctors and medical practices in a variety of identity theft and financial fraud scenarios, I strongly suggest you **check your credit** at least bi-annually, get some kind of active credit monitoring and do it soon

**if you have not done so in the last six months**. The end of the year and tax time are two of the most active seasons for fraud.

## Employee Embezzlement Issues

Employee theft and embezzlement poses a serious threat to medical practices and their owners. There are many ways to spot and prevent employees from helping themselves to your practice's revenue some are complex, others are simple and should be "best practices" and part of loss prevention for any business.

Last year we addressed a variety of serious legal and financial exposures related to your practice's employees suing you, including the importance of a professionally drafted employment manual, and specialty employment insurance your HR program must include. Other forms of employee related liability exist as well, like theft and embezzlement, which can put you in harm's way beyond just the loss of the funds themselves, as in cases where an employee may be using patient financial data

My friend, attorney Charlie Davis, is the founding partner of the multi-state law firm of Davis Miles McGuire Gardner in Phoenix, Ariz. and has also seen many of these issues in his four decades of business law practice. He shared many of his experiences with me as part of my research on this issue.

Small businesses, which account for the status of many medical practices, are often higher risk, softer targets for scammers due to accounts payable and accounting systems that lack many of the formal checks and balances bigger businesses use to control embezzlement losses. As a result, **American businesses like yours lose as much $120 billion a year to this kind of fraud.** One client discovered an administrative employee had stolen over $250,000 over three years through a variety of invoicing scams, money that would have helped keep the business out some substantial financial jeopardy when then went through lean times during the recession.

**ACCOUNTING AND FINANCED BASED RED FLAGS**

• Discrepancies between daily receipts and daily bank deposits

• Increased purchases in disposable supplies and services

• Repeating account or invoice numbers used in duplicate billings and/or invoices (or numbers that follow an unusual pattern)

• Unplanned and unusual changes in expenses, costs or inventory

• Sudden or unseasonal drops in profit margins, gross, net, etc.

• Unreasonable travel expenses

• Changes in receivables patterns including collections, write-offs, slow-pays, etc.

• Obvious and repeated alterations, changes, whiteouts (or omissions) to sales slips, accounts payable, accounts receivable, inventory figures, etc.

• Lost, damaged, or missing documents

• Unusual credits to patients on a recurring basis

If you spot any of the above issues, look more closely at the following behavior patterns to help identify who the problem may be. Remember, statistically the perpetrators are likely to be "nice people" whom you would not ordinarily expect, including possibly your partners and executives. **The higher the person is on the food chain, the bigger the amount they typically steal, so partners and executives may steal $500K or more, where as administrative employees often steal less than $100K.** Some of these people have financial issues, some are just looking for an easy buck, some have a gambling problem, and others may just resent what they think you have or make, or how they feel treated, there is no "obvious thief" in most cases.

**BEHAVIORAL RED FLAGS: PARTNERS AND EMPLOYEES**

• Familiar or unusually social relationships with customers or suppliers

• Sudden and inexplicable changes in lifestyle or spending (up or down)

• Heightened interest in practice finances unrelated to an employee's job or compensation

• Personal financial issues (including divorce, bankruptcy, signs of substance abuse, debt issues, etc.)

**Specific Scams: Just a Few of Countless Examples**

We started by providing you accounting and behavioral and accounting based red flags to watch for before we provided details of any specific fraud schemes because no list can ever be complete. Use the patterns we've provided above to help identify need for concern, then focus on any specific methods the problem employee or partner may be using.

1. **Overwriting:** In this scam an employee overwrites checks to vendors and pockets the refunds or they overwrites the invoice itself and keep the overage to the vendor, often with vendor participation.

2. **Traditional Theft:** Not all crime involves the internet, this "old-fashioned" kind of theft is commonly accomplished in one of two ways: failing to record cash sales or checks and pocketing the money or simply stealing from the

cash register, and making changes on the printouts or tapes.

One brazen thief even ran patient credit cards on her cell-phone credit card reader, that went to her own fake business account. Of course, patient payments may also be intercepted and stolen before your office ever sees them as well, so watch for unusual offsets in discounts, collections and credits.

3. **Wage Theft:** Healthcare providers should watch for padded hours, false pay rates, and even phony employees, where one employee can punch two or more time cards. It should be clear to the entire organization that someone monitors these issues and knows who every person getting a paycheck is, what they do and that they exist. If not, you may also have other issues like your HR polices, credentialing and other regulatory issues.

4. **Employment lawsuits:**

- Disability
- General frivolous claims
- Wage
- Contract/Compensation
- Separation based suits, retention, practice sales

## Insurance

Insurance is a key part of any asset protection strategy and this area requires several layers to be adequately protected. All **polices and agents are not equal**, make sure you are working with an experienced commercial insurance agent that actually understands the market and policy details of the various specialty insurance polices you need. It is typically my preference that my own clients work with **multi-line brokers** that have access to multiple A-rated carriers they can pick and chose from to get you the perfect mix at the best pricing.

a. **D&O insurance.** In some cases you may have some personal, executive liability to third parties, patients and even your business partners for your acts or omissions that may have contributed to a loss. Protect yourself with a seven figure "directors and officers" insurance policy that, if nothing else, will cover the costs of your legal defense that can quickly reach six figures;
b. Have **commercial casualty/loss insurance** that adequately addresses your losses from both internal and external theft;
c. Get high limit **EPLI** (Employment Practices Liability Insurance) that will help cover your legal costs on both lawsuits by employees and in some cases your own liability with third parties due to your employee's unpermitted conduct;
d. Have **Data Breach/Cyber Liability Insurance** of at least $1MM in case your exposure originates or includes electronic payment or EHR.

In closing, the first line of defense is always YOU. Being a good leader and having good managers that pay attention to detail, enforce rules and polices on all these issues and who randomly cross check inventory, deposits, receipts and expenses is the most predictable and cheapest line of defense. You can control much of this exposure by eliminating temptation by removing the opportunity and using our three-step system as start to your practice financial security review. Finally, don't let this make you paranoid, most people, given the opportunity want to work hard and please you, create the conditions for them to do so by being informed and prepared.

## SELF EVALUATION

### Fighting Fraud and Embezzlement in the Medical Practice

**1.** Which of the following are behavioral red flags?

a. Changes in lifestyle
b. Possible addiction issues
c. Unusual interest in practice cash flow and earnings
d. Never taking time off
e. All of the above
f. None of the above – we can't judge people

**2.** Which are practice related fraud schemes you need to be aware of?

a. Overwriting invoices
b. Padded hours and wage fraud
c. Ponzi and Pyramid Schemes
d. Theft of goods and supplies
e. Fake or cloned invoices
f. a, b, d and e

**3.** Which forms of insurance can help with these risks?

a. Geico
b. A personal umbrella policy for $1MM or more
c. Data Breach and Cyber liability
d. Employment practices insurance
e. General liability Insurance
f. D&O insurance and C,D, ad E

**4.** True/False - I know how my own practice pays vendor bills and manages invoices, purchases and inventory:

**5.** Which of the following is not on our list of important procedural safeguards?

a. Screening employees
b. Random audits of inventory, payments, receivables and deposits
c. Using numbered checks and purchase orders
d. Only having one person in charge of all financial details for accountability

**6.** Fraud and Embezzlement creates which of the following risks?

a. All of the following
b. Third party legal risk with patients
c. Risk from my partners for breach of legal fiduciary duty
d. Financial solvency risk
e. Internal risk from employees who may be accused or have their own identity stolen

**ANSWER KEY:** 1. E, 2. F, 3. F, 4. Self awareness - no right answer, 5. D, 6. A

## Dilip K. Moonka, MD, FAST, FAASLD

Dilip K. Moonka, MD, FAST, FAASLD, of Detroit, Michigan, is medical director of Liver Transplantation at Henry Ford Hospital in Detroit. Dr. Moonka received his medical degree from Stanford University where he also completed his residency in internal medicine. He received his training in gastroenterology and hepatology at the University of Pennsylvania and is board certified in internal medicine, gastroenterology and transplant hepatology. Dr. Moonka has won numerous teaching awards in both the Department of Medicine and the Division of Gastroenterology and he conducts clinical research in both liver transplantation and viral hepatitis with numerous publications in both areas. Dr. Moonka is a Fellow of the American Association for the Study of Liver Disease (FAASLD) as well as the American Society of Transplantation (FAST), and he speaks or consults for Bristol-Myers Squibb, Gilead, Intercept and Merck.

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## Evaluating Liver Function Tests

### LIVER "FUNCTION" TESTS

- LFT's must be interpreted in the context of the individual patient and their clinical setting
- To increase both the sensitivity and specificity of laboratory tests in the detection of liver disease, it is essential to use them as a battery

### LIVER "FUNCTION" TESTS

- They are a useful noninvasive screening tool for the presence of liver disease
- They may point to a specific diagnosis
  - Pattern recognition is key
- Allow clinicians to assess the severity of liver dysfunction
- In patients with established liver disease, they can help identify improvement, progression or response to treatment

### THE DIFFERENT PATIENTS

- The patient with persistent or chronic LFT abnormalities
- The patient with marked acute LFT abnormalities
- The patient with known chronic liver disease

### THE FEATURED PLAYERS

- AST, ALT
- ALKALINE PHOSPHATASE
- BILIRUBIN

### THE CHARACTER ACTORS: ASSESS HEPATIC FUNCTION

- BILIRUBIN
- ALBUMIN
- PROTIME

### PATTERNS OF HEPATIC INJURY

- HEPATOCELLULAR
- CHOLESTATIC
- MIXED

## THE AMINOTRANSFERASES: ALT AND AST

- Use to be called the SGPT and SGOT
- Facilitate gluconeogenesis from protein sources
- The AST can be found in cardiac and skeletal muscle whereas the ALT is more specific to liver
- The ALT and AST are markers of hepatocellular injury

## THE AMINOTRANSFERASES: ALT AND AST

- Chronic hepatitis is defined as an ALT that is elevated for greater than 6 months
- In 30-50% of apparently healthy individuals, an isolated, elevated ALT will be normal on repeat
- Minor elevations may occur in virtually all forms of liver disease and should be evaluated to exclude treatable forms of liver disease

## THE AMINOTRANSFERASES: ALT AND AST

- Typically elevated in most forms of liver disease
- Mild elevations can be seen in cholestatic liver disease
- Highest elevations occur in viral and drug-induced hepatitis
- The AST to ALT ratio may be helpful in diagnosing alcoholic hepatitis
- Height of elevation reflects degree of hepatocellular injury for most diseases except alcoholic liver disease and hepatitis C

## ALKALINE PHOSPHATASE

- It's physiologic role is ?
- It is typically considered a marker of cholestatic liver disease because it is preferentially made by biliary epithelium
- Various sources: liver, bone, intestine, kidney, placenta and white cells
- The GGT can be used to determine if the liver is the source of an elevated alk phos

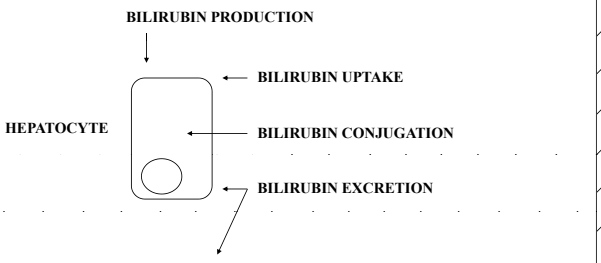
## ALKALINE PHOSPHATASE

- 75% of patients with prolonged cholestasis have alkaline phosphatase values 4X normal
- Height of elevation does not distinguish intra vs extrahepatic obstruction
- Less than 3X elevation may occur in most liver diseases
- Low levels may be seen in Wilson's disease

## BILIRUBIN

- Organic anion that results from breakdown product of red cells
- Transport in blood requires noncovalent binding to albumin
- Taken up across hepatocyte membrane by carrier-mediated transport (excludes albumin)
- Undergoes conjugation with glucuronic acid to form bilirubin monoglucuronide and diglucuronide (direct bilirubin)
- Bilirubin conjugates actively transported form hepatocyte into canalicular bile (rate limiting step in excretion)
- Conjugated bilirubin drains into intra-extrahepatic bile ducts into duodenum
- Hydrolyzed to unconjugated bilirubin in distal ileum and colon (80% excreted feces, 20% absorbed, fraction filtered by kidney as urobilinogen)

## HYPERBILIRUBINEMIA




## HYPERBILIRUBINEMIA

- Overproduction
  - Hemolysis
  - Transfusion
  - Hematoma, internal bleeding
- Impaired uptake
- Impaired conjugation
  - Parenchymal disease
  - Drugs
  - Passive congestion
- Impaired excretion
  - Sepsis
  - Extrahepatic obstruction
  - Pancreatic disease, Cholecystitis

## BILIRUBIN: DIRECT VS INDIRECT

- In the evaluation of jaundice, the presence of direct bilirubin suggests that hepatocytes are functioning.
- Jaundice from biliary obstruction gives almost all direct bilirubin
- High levels of indirect bilirubin is typical of Gilbert's disease or hemolysis
- It is unusual to get a bilirubin over 30 mg/dl without renal insufficiency

## ALBUMIN

- Synthesized exclusively by the liver
- It has a half-life of 20 days and is not reliable indicator of function in acute liver disease
- Albumin less than 3 should raise the suspicion of chronic liver disease
- May be low in non-hepatic disease: protein-losing enteropathies, chronic infection, nephrotic syndrome

## THE PROTHROMBIN TIME (PT)

- One of the outstanding and most useful tests of hepatic function.
- Critical test in monitoring hepatic function in both acute and chronic hepatitis
  - Fulminant hepatic failure
  - Decompensation of chronic liver disease
- Not a sensitive index of liver disease
- A prolonged PT is not specific for liver disease: congenital factor deficiencies, DIC, medications, nutritional deficiency

## WHAT ARE YOU LOOKING FOR?

- STEATOHEPATITIS
- ALCOHOL
- VIRAL HEPATITIS
- DRUG INDUCED LIVER INJURY (DILI)
- AUTO-INFLAMMATORY CONDITION

## WHAT ARE YOU LOOKING FOR?

- METAL DEPOSITION
- OBSTRUCTIVE
- MALIGNANCY
- INFECTION
- ALPHA-1 ANTITRYPSIN DEFICIENCY
- SYSTEMIC (CARDIAC)
- VASCULAR (ISCHEMIA, THROMBOSIS)

## THE PATIENT ENCOUNTER

- Patient history is critical
  - Risk factors, exposures
  - Medications, alcohol, drugs
  - Symptom history, systemic illness
  - History of previous elevation, jaundice
  - Family history
- Historical information of liver tests is critical
  - Acute vs chronic
  - Response to treatment, change in clinical condition or medication
- Pattern recognition is critical

## RISK FACTORS FOR VIRAL HEPATITIS EXPOSURE

- Sexual Activity
- Intravenous, intranasal and inhaled drug use
- Transfusions
- Needlestick
- Workplace: Institutions, Day care, Hospitals
- Travel
- Tattoos and body-piercing

## LIST OF POTENTIAL TESTS: "Rounding Up the Usual Suspects"

- Hep A IgM, HBsAg, Hep C Ab, Hep C PCR, monospot, HIV, EBV IgM and IgG
- Serum iron, TIBC, ferritin, ceruloplasmin
- ANA, AMA, ASMA, LKM
- Cholesterol, HGB A1C, alpha-1 antitrypsin, angiotensin converting enzyme, alpha-fetoprotein, celiac panel
- TSH
- Abdominal ultrasound

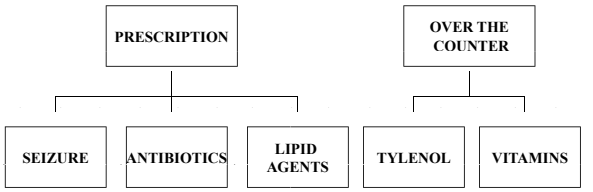
## NON-ALCOHOLIC FATTY LIVER DISEASE (NAFLD)

- CLUES
  - Middle aged individuals
  - High body mass index (BMI)
  - Diabetes or hyperlipidemia
- SCREEN
  - Cholesterol, hemoglobin A1C
  - Round of the "usual suspects"
- DIAGNOSIS
  - Liver biopsy

## VIRAL HEPATITIS

- Hepatitis A IgM
- Hepatitis B surface antigen (HBsAg)
- Hepatitis C antibody or PCR
- Hepatitis E IgM

## DRUG INDUCED LIVER INJURY (DILI): MEDICATIONS




## ANTIBICROBIAL AGENTS

| AGENT | INJURY |
|---|---|
| CLINDAMYCIN | H |
| ERYTHROMYCIN | C |
| AMOXICILLIN | H |
| AMPICILLIN | H |
| AUGMENTIN | C |
| TETRACYCLINE | STEATOSIS |
| BACTRIM | C,H |
| AMPHOTERICIN | H |
| KETOCONAZOLE | H |

H:HEPATOCELLULAR
C:CHOLESTATIC
AT:ALT ELEVATION

## MEDICATIONS WITH DISTINCT LIVER INJURY

- Nitrofurantoin
- Amiodarone
- Anabolic Steroids
- Azathioprine

## DRUG INDUCED LIVER INJURY livertox.nih.gov

- NIH sponsored website
- Easy to use and comprehensive
- Includes herbal and dietary supplements

## AUTO-INFLAMMATORY CONDITIONS OF THE LIVER

- Autoimmune Hepatitis
- Primary Biliary Cirrhosis
- Primary Sclerosing Cholangitis
- Overlap Syndromes
- Sarcoidosis

## AUTOIMMUNE CHRONIC ACTIVE HEPATITIS

- CLUES
  - Women affected more than men
  - Elevations in aminotransferases
  - Associated autoimmune disorders
  - Non-specific symptoms of fatigue and malaise
- SCREEN
  - ANA, ASMA, Anti-LKM
  - SPEP, Quantitative immunoglobulins
- DIAGNOSIS
  - Response to steroids typically confirmatory

## PRIMARY BILIARY CIRRHOSIS

- CLUES
  - Middle aged women
  - Fatigue, pruritus, jaundice may be common
  - Elevated bilirubin and alkaline phosphatase
  - Over 90% of patients will have alk phos > 2 fold elevated
- SCREEN
  - AMA positive in 95%
- DIAGNOSIS
  - Biopsy showing granulomas, bile duct destruction

## PRIMARY SCLEROSING CHOLANGITIS

- Chronic inflammation and destruction of intra-extra hepatic bile ducts
- Cholestatic picture predominates
- Clues
  - 50-75% will have associated inflammatory bowel disease
  - Recurrent cholangitis
- Diagnosis
  - MRCP/ERCP

## HEMOCHROMATOSIS

- CLUES
  - Liver disease in association with
    - Skin bronzing
    - Cardiomyopathy
    - Conduction disturbances
    - Diabetes
    - Testicular atrophy
    - Arthropathy
    - Impotence
    - Family History
- DIAGNOSIS
  - Iron, TIBC, Ferritin
  - Genetic testing: HFE gene
  - Liver biopsy

## REPRESENTATIVE IRON STUDIES

| | NORMAL | HEMOCHROMATOSIS |
|---|---|---|
| IRON | 50-150 | 180-300 |
| TIBC | 250-370 | 200-300 |
| % SATURATION | 20-50 | 80-100 |
| SERUM FERRITIN | | |
| WOMEN | 15-250 | 500-6,000 |
| MEN | 20-300 | 500-6,000 |
| HEPATIC IRON CONCENTRATION | 300-1,800 | 10,000-30,000 |

## WILSON'S DISEASE

- CLUES
  - Liver disease in younger patients
  - Liver disease with hemolysis
  - Neuropsychiatric disease
  - Kayser-Fleicher rings
  - Family history
- SCREEN
  - Serum ceruloplasmin
- DIAGNOSIS
  - 24 hour urinary copper, liver biopsy for quantitative copper

## ALPHA-1-ANTITRYPSIN DEFICIENCY

- CLUES
  - Chronic active hepatitis
  - Cirrhosis
  - Precocious emphysema
- SCREEN
  - Alpha-1 antitrypsin level
- DIAGNOSIS
  - Genotype: M is normal allele and Z and S are abnormal
  - Liver biopsy showing inclusion granules

## PATTERNS OF HEPATIC INJURY

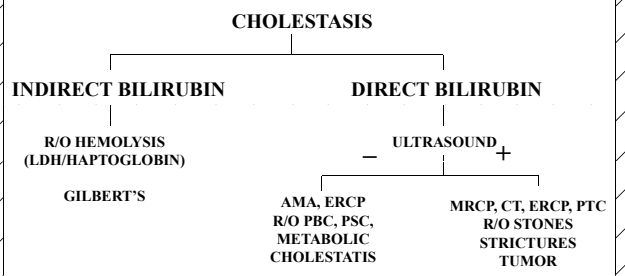
- HEPATOCELLULAR
- CHOLESTATIC
- MIXED

## ACUTE HEPATITIS:
An ALT or AST over 1000 U/L Has Four Causes

- VIRAL HEPATITIS
- DRUGS OR TOXINS
- ISCHEMIC HEPATITIS
- AUTOIMMUNE HEPATITIS
- CHOLANGITIS

- The protime is the critical test for monitoring

## ALGORITHM




## METABOLIC CHOLESTASIS

- Sepsis/inflammation
- Blood products, hemolysis, hemorrhage
- Anesthesia
- Parenteral nutrition
- Cardiovascular surgery
- Passive congestion
- Ischemia
- Medications
- Renal insufficiency
- Infitrating hepatic disease

## WHEN YOU SEE A MIXED CELLULAR AND CHOLESTATIC PICTURE- THINK!

# MEDICATIONS

## ASSESSMENT OF CHRONIC LIVER DISEASE

- Bilirubin
- Albumin
- Protime
- Platelet Count

## CHILD-PUGH CLASSIFICATION OF THE SEVERITY OF LIVER DISEASE

| | 1 Point | 2 Point | 3 Point |
|---|---|---|---|
| BILIRUBIN (mg/dl) | < 2 | 2-3 | >3 |
| ALBUMIN | >3.5 | 2.8-3.5 | <2.8 |
| PROTIME (seconds above normal) | 1-4 | 4-6 | >6 |
| ENCEPHALOPATHY | Absent | Mild - moderate | Severe |
| ASCITES | Absent | Slight | Moderate |

Score of 5-6: Child's Class A
Score of 7-9: Child's Class B
Score of > 10: Child's Class C

## THE MELD SCORE

R=0.625log(Cr)+0.710log(Bili)+1.35log(INR)= MELD

- Scores range from 6 (least ill) to 40 (critical)
- Predicts 90 day mortality
- Priorizes patients for liver transplant

| | |
|---|---|
| • MELD 10-19 | 6% |
| • MELD 20-29 | 19.6% |
| • MELD 30-39 | 52.6% |
| • MELD 40 | 71.3% |

## CASE STUDY 1

- 35 year old woman referred to you for elevated liver tests:
  - AST 280
  - ALT 160
  - Alkaline Phosphatase 1.5 times normal
  - Serum Bilirubin normal

## CASE STUDY 1

- Complains of one year of mild fatigue
- Risk factors for viral hepatitis negative
- Only medication traditionally is levoxyl
- Recently started on lovastatin for 3 year history of hyperlipidemia

## CASE STUDY 1

| **Previous ALT 2.5X normal 1 year prior** | **Previous ALT normal 1 year prior** |
|---|---|
| **Differential Diagnosis** | **Differential Diagnosis** |
| **Autoimmune hepatitis** | **Lovastatin** |
| **Fatty liver** | **Fatty liver** |
| **Doubt lovastatin** | **Autoimmune hepatitis** |

## CASE STUDY 2

- 48 year old man referred for abnormal liver tests
  - AST 86
  - ALT 30
  - Alkaline Phosphatase 480
  - Serum Bilirubin 1.2 (Direct 0.9)
  - Albumin 3.3
  - Prothrombin time 14.2 seconds
- Admits to “drinking a bit”
- Episodic epigastric pain

## CASE STUDY 2

- Numbers improve marginally off alcohol
- Viral and autoimmune serology's are negative
- Abdominal ultrasound shows no gallstones or dilated bile duct but head of pancreas appears atrophic with calcification

## CASE STUDY 3

- 23 year old male college student presents with "yellow eyes"
- Notes sore throat, myalgia, low-grade fever
- Notes he is sexually active with new girlfriend and had similar episode 5 years ago
  - AST 33
  - ALT 28
  - Alkaline Phosphatase 110
  - Bilirubin 5.3

## CASE STUDY 3

- Viral and autoimmune serology's are negative
- Direct bilirubin is 0.7
- Indirect bilirubin is 4.3

## CASE STUDY 4

- You have followed a 43 y/o man from Taiwan with hepatitis B
- He did not respond to interferon and has biopsy proven cirrhosis
  - Albumin 3.3 g/dl
  - Protime 12.6 sec
  - Bilirubin 1.8 mg/dl
  - Platelet count 49

## CASE STUDY 4

- He asks to see you urgently because he does not feel well and notes his urine is dark
- On physical exam he does have muscle wasting and scleral icterus
  - Albumin 2.8 g/dl
  - Protime 17.4 sec
  - Bilirubin 6.2 mg/dl
  - Platelet count 44

SELF EVALUATION

## Evaluating Liver Function Tests

**1.** Which is true of the AST and ALT:

a. They are good tests of liver damage because they are made exclusively in the liver
b. The ALT to AST ratio is elevated in alcoholic liver disease because AST is depleted by chronic alcohol use
c. Minor elevations of the AST and ALT are usually not indicative of significant liver disease and do not require evaluation
d. Modest elevations in the AST and ALT can be seen with cholestatic liver disease
e. If an AST or ALT is elevated on a single occasion and then returns to normal, no further evaluation should be done

**2.** Which is true of the bilirubin:

a. With obstructive jaundice, most of the bilirubin elevation is direct
b. Gilbert's disease is caused by the absence of glucuronyl transferase
c. Bilirubin results from the breakdown of red cells
d. A and C
e. All of the above

**3.** Common tests performed in the evaluation abnormal LFTs include all except:

a. C-reactive protein
b. Celiac panel
c. Anti-mitochondrial antibody
d. Hepatitis C antibody
e. Hemoglobin A1C

**4.** Which statement is not true of drug-induced liver injury:

a. A small percent of patients taking statin drugs will experience elevated LFTs because of them
b. Antibiotics are an unusual cause of drug induced liver injury
c. Nitrofurantoin can cause a hepatotoxicity that can resemble autoimmune hepatitis
d. Anabolic steroids can be associated with cholestatic liver disease
e. Depakote and phenytoin can be associated with severe hepatotoxicity

**5.** Which statement is correct about the MELD score

a. The MELD score incorporates the bilirubin, INR and albumin
b. The Child-Pugh score more accurately predicts 90 day mortality than the MELD score because it incorporates encephalopathy and ascites
c. A patient with a MELD score of 15 has a 90 day mortality of 20%
d. The MELD score was devised at the National Institutes of Health
e. The MELD score is used to prioritize patients for liver transplant

**6.** True/False - Ultrasound is not a good test for bile duct dilation and obstruction?

**7.** True/False - The GGT test can help determine if alkaline phosphatase is from liver, bone or white cells?

**Answer Key:** 1. D, 2. D, 3. A, 4. B, 5. E, 6. F, 7. T

## Elizabeth W Woodcock, MBA, FACMPE, CPC

Elizabeth W Woodcock, MBA, FACMPE, CPC, of Atlanta, Georgia, received her bachelor's degree, summa cum laude, from Duke University, and earned an MBA from The Wharton School of Business at University of Pennsylvania. She has worked professionally in the healthcare management field for over 25 years and is a nationally renowned speaker, consultant and author. Ms. Woodcock is a principal of Woodcock & Walker Consulting and has written dozens of books, chapters, articles and white papers including *The Physician Billing Process: Avoiding Potholes in the Road to Getting Paid: Third Edition, 2015*, and *Mastering Patient Flow to Increase Efficiency and Earnings: Fourth Edition, 2017*.

You may contact Ms. Woodcock with your questions and comments at 404-373-6195, or by email at Elizabeth@ElizabethWoodcock.com.

woodcock & associates
CHANGING THE WAY YOU WORK

**Effective Revenue Cycle Management - Part 1: Before and During the Encounter**

***Elizabeth W. Woodcock, MBA, FACMPE, CPC***

## Agenda

- Call to action
- Strategy
- Pre-visit
- Time-of-service



## Call to Action

**New Payer in the Market**


**Your Patient**



## Call to Action

Affordable Care Act's Healthcare Exchange

Majority of Enrollees have Chosen the "Bronze" Plan (Highest Patient Responsibility)

More and More Insurers have Narrowed their Networks – and Limited Out-of-Network Benefits

**More Patient Financial Accountability**

Employers are Choosing to Offer More Plans with High Deductible Options at a Lower Cost – Employees are Buying

Insurers are Limiting Coverage Where Possible – and Increasing Referral/Authorization Requirements



## Call to Action

Collecting from patients costs 2 times what it costs to collect from a payer!!

**~$8,000 per provider**

[1]*$7,931, based on 25 patients per day, 47 weeks per year, 4.5 days per week, 2 statements per patient @ $.75 per statement in processing and mailing costs.*



## Call to Action

**The market has changed – so you must align your processes accordingly**




## Strategy

- Define what you are <u>allowed</u> to collect
  - Coinsurance
  - Unmet deductible
  - Non-covered services
  - Pre-service payments

## Strategy

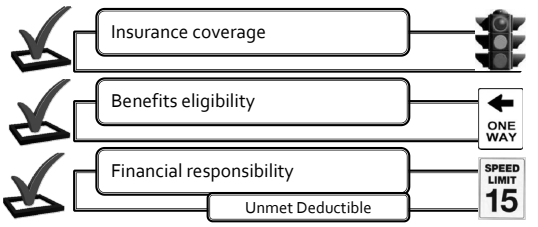

**Minimum**

- **Copayments**
- **Full-pay deposits**
- **Balances**




## Pre-Visit


**Financial Clearance**






## Pre-Visit

- Initial scheduling call
- Appointment confirmation
- When patient presents

**"Arrival Time"**



## Pre-Visit

✓ **Dual Monitors**



## Pre-Visit

- Appointment scheduling and confirmation
  - Reveal expectations regarding time-of-service payment
  - Collect balances
  - Request pre-payment for scheduled services*

***Check with your payer contracts regarding ability to collect on a pre-service basis. If concerns, state: "This is a voluntary pre-payment. It will be refunded to you in the event that your insurance pays more than is estimated or in full." Consult with an attorney.***



## Pre-Visit

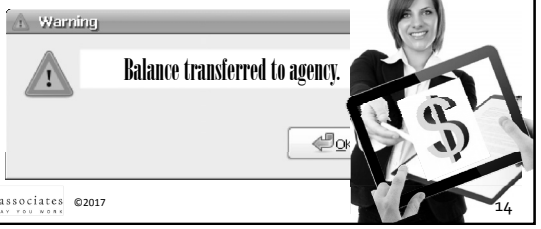
## Pre-Visit


**<u>Every</u> Employee of Your Practice is a Member of the "Business Office"**



## Pre-Visit

- Don't limit yourself to "past"-due balances
- Train staff to collect bad debt
  - How to identify it
  - Reverse the bad debt and apply the payment






## Time-of-Service

'If not, why not' report

| Patient | Amt Due | Status of Collection |
|---|---|---|
| 7:45 a.m. Janet Jones | $10 | |
| 8:15 a.m. Ellie Scot | $123.45 | |
| 8:30 a.m. Cade Williams | $0 | |
| 8:45 a.m. Virginia Jacobs | $45.21 | |

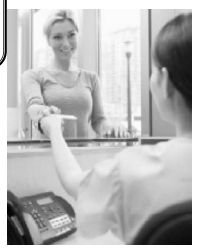


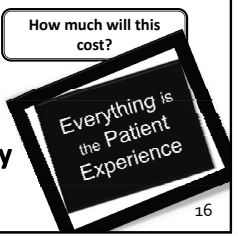

## Time-of-Service

When you bring up money, you don't care about me

When you can't tell me what I owe, you don't care about me

How much will this cost?






⇨ **Transparency**



## Time-of-Service




*We appreciate your choosing Dr. Smith for your health care. The cost of your visit may vary, as Dr. Smith may decide that she needs to order some tests or other services may be necessary to help her provide you with the best care. As an estimate, an appointment with Dr. Smith typically costs $250 to $500. Because I see that we contract with your insurance company, you will receive a* ***discount****. I strongly recommend that you contact your insurance company to determine the status of your out-of-pocket responsibility. Their phone number is on the back of your insurance card.*



## Time-of-Service

**What is a "contractual adjustment"??**

## Time-of-Service

**Financial Worksheet**

You are scheduled for a XXXX on May 4, 2018. We will file the claim for this service with your insurance company, ACME INSURANCE. This financial worksheet outlines the estimated cost of the surgery*, your discount and financial responsibility, and what your insurance company is estimated to pay on your behalf.

Estimated Cost of Your Surgery:

**Your Discount: $XXX.XX (XX%)**

Your Financial Responsibility:

Your Insurance is Estimated to Pay:

50% of your financial responsibility is due prior to the date of the surgery. We would be happy to accept cash, check or charge. The remainder is due within 90 days after the date of the surgery. There is a $200 charge that will be applied to your account in the event that you do not present for your surgery. This charge will be deducted from any refund due as a result of the cancelled surgery.

Plan of Payment:

If you have any questions regarding your insurance coverage or your financial responsibility, which is assigned by your coverage, please contact your insurance company at 800-888-8888. We recommend that you have your insurance card handy when you speak with them.

Signed (Patient): _____

Orange!!

*This agreement is for the surgeon only. You may receive bills from the hospital and other health care providers. Please note that this financial agreement outlines our best estimate for what will be performed, however, additional or different procedures may be necessary to complete the treatment. We follow the national coding guidelines as issued by the American Medical Association. The estimate includes customary post-operative care in our office. Your follow-up care may result in additional appointments for unforeseen circumstances, and these may result in additional financial responsibility.

## Time-of-Service

**Practice Associates**

| CPT | Description | Practice Charge/Fee | Allowable Medicare | Allowable Blue Shield | Allowable MCO One | Allowable MCO Two |
|---|---|---|---|---|---|---|
| 99201 | Office/outpatient visit, new | | | | | |
| 99202 | Office/outpatient visit, new | | | | | |
| 99203 | Office/outpatient visit, new | | | | | |
| 99204 | Office/outpatient visit, new | | | | | |
| 99205 | Office/outpatient visit, new | | | | | |
| 99211 | Office/outpatient visit, est | | | | | |
| 99212 | Office/outpatient visit, est | | | | | |
| 99213 | Office/outpatient visit, est | | | | | |
| 99214 | Office/outpatient visit, est | | | | | |
| 99215 | Office/outpatient visit, est | | | | | |

**Better? Automate the Process**



## Time-of-Service

Requires staff who can collect:


1. Mr. Walker's health plan has an allowance of $83.25 for his office visit which was a 99212. His health plan requires a 20% coinsurance. How much does he owe?
2. Mr. Wood does not have insurance for his family, but he would like to take advantage of your discount for uninsured patients who pay in full at the time of service. His bill is $213, and your practice offers a 30% discount for payment in full. How much does he owe if he pays in full today?

1. Answer: $16.65
2. Answer: $149.10

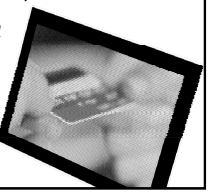


## Time-of-Service

**How would you like to take care of your copayment today, Ms. Jones?**

*"Ms. Jones, our practice's policy is to request payment at the time of service. Your insurance plan requires a copayment of $_____. Will you be paying with cash, check, or credit card?*

[Wait for card.] *I also note that you have a **small** balance of $_____. Can we go ahead and run your card to take care of that balance?"*



*Source: E. Woodcock, Front Office Success, MGMA, 2010 (www.mgma.com)*



## Time-of-Service

- Precede the question with a compliment
- Use the patient's name
- Look the patient in the eye
- Demonstrate that you expect payment
  - Write out the receipt
- Accept all forms of payment




## Time-of-Service

- Offer lending options
  - External vendor
  - Internal payment plan
    - Parameters (time and amount): e.g., 6 months; $25
    - Create plans using twice-monthly payments (lower)

***"How much more time do you need?"***

**Create a separate financial class for payment plans**

## Time-of-Service

Payment Mechanism on File

Secure collection of credit card information

- "Credit Card On File"
  - Pre-authorized credit card transactions
  - Mechanics? Credit card is swiped and held securely; payment plan or one-time charge after insurer has paid



25

## Conclusion


***"Thank you for choosing Practice Associates for your care."***



26

SELF EVALUATION

**Effective Revenue Cycle Management - Part 1: Before and During the Encounter**

**1.** It is important to communicate expectations with regards to financial clearance prior the patient's _____?

a. Arrival
b. Prescription is filled
c. Post-operative appointment
d. Test results notification

**2.** Basic math skills are critical for employees who are hired to pursue time-of-service collections. Mrs. Jones does not have insurance, but she would like to take advantage of your discount for uninsured patients who pay in full at the time of service. Her bill is $234, and your practice offers a 30% discount for payment in full. How much does she owe if she pays in full today?

a. $70.20
b. $163.80
c. $170.20
d. $226.98

**3.** Before you get started in optimizing your collections at the time of service, be sure to:

a. Hire five more employees
b. Revamp your Website
c. Define what you are allowed to collect
d. Call a credit card company

**4.** A sign of appreciation upon receiving payment by a patient, you should always say:

a. "Our printer is broken, but we will mail the receipt to you, Ms. Jones"
b. "If there is a remaining balance, I will contact you in a few months, Ms. Jones"
c. "Your payment will pay for the staff's holiday party, Ms. Jones"
d. "Thank you for paying your bill, Ms. Jones"

**5.** Inaccurate information collected from the patient during the registration process leads to all of the following but one:

a. Improper amounts collected at the time of service
b. Denied claims
c. Outdated CPT® codes
d. Incorrect patient statements

SELF EVALUATION

**Effective Revenue Cycle Management - Part 1: Before and During the Encounter cont.**

**6.** Before setting up a payment plan, ask the patient the following question:

a. "What time is it?"
b. "How many statements would you like?"
c. "How much more time do you need?"
d. "How much money would you like to pay?"

**7.** A report to hold employees accountable for the job of time-of-service collections is called:

a. Time-of-service payment dashboard
b. 'If not, why not' report
c. Profit and loss statement
d. Pre-visit chart review checklist

**8.** A "contractual adjustment" is a billing term that really means _____ from the patient's perspective.

a. Discount
b. Fee schedule
c. Allowable
d. Unmet deductible

**9.** The employees at your practice who schedule appointments should be prepared to answer the patient's question:

a. How much will this cost?
b. What is the temperature of your exam rooms?
c. What housekeeping service do you use?
d. How many lab tests will you order?

**10.** To request time-of-service payments, you should ask patients:

a. Would you like to pay your copayment?
b. How would you like to take care of your copayment?
c. Would you like for us to bill your insurance company first?
d. Would you like to call your human resources office?

**11.** A minimum deposit for patients without insurance is:

a. A method to capture a down payment on your building's rent.
b. A strategy to dismiss patients from your practice.
c. A reasonable manner of collecting some, if not all, of the payment from an uninsured patient at the time of service.
d. Not necessary to collect at time of service.

**12.** Patient financial clearance includes processes to:

a. Confirm active insurance coverage only
b. Confirm active insurance coverage; verify benefits eligibility; and determine financial responsibility (including unmet deductibles)
c. Verify benefits eligibility only
d. Determine financial responsibility (including unmet deductibles) only

**13.** T/F - You should *only* make attempts to collect balances that are more than 120 days outstanding at the time-of-service.

**Answer Key:** 1. A, 2. B, 3. C, 4. D, 5. C, 6. C, 7. B, 8. A, 9. A, 10. B, 11. C, 12. B, 13. F

## Barry A. Franklin, PhD

Barry A. Franklin, PhD, of Royal Oak, Michigan, is director of Preventive Cardiology and Cardiac Rehabilitation at William Beaumont Hospital which, during his tenure, has achieved national recognition in the diagnosis and treatment of coronary artery disease. He served as president of the American Association of Cardiovascular and Pulmonary Rehabilitation (1989–1990) and of the American College of Sports Medicine (1999–2000).

Dr. Franklin is a past editor in chief of the *Journal of Cardiopulmonary Rehabilitation* and currently holds formal editorial board appointments with 15 other scientific and clinical journals. He has written or edited nearly 600 scientific and clinical publications, including 27 books and, since 1976, he has given over 1,000 invited presentations to state, national and international audiences. In 2015 Dr. Franklin was listed by Thomson Reuters among *The World's Most Influential Scientific Minds (Clinical Medicine)*, something quite rare for a non-physician.

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Barry A. Franklin, PhD
Director of Preventive Cardiology and Cardiac Rehabilitation

## Moving from Reactive Sick Care to Proactive Healthcare

The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

SHATTUCK LECTURE

We Can Do Better — Improving the Health of the American People

Steven A. Schroeder, M.D.

**N Engl J Med 2007;357:1221-8**

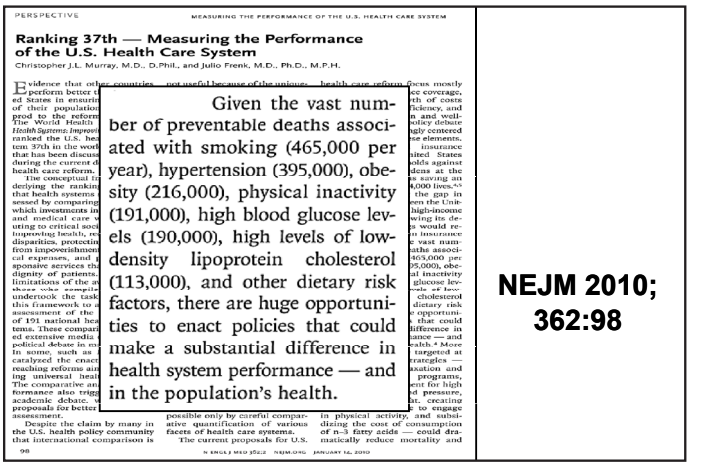
THE UNITED STATES SPENDS MORE ON HEALTH CARE THAN ANY OTHER nation in the world, yet it ranks poorly on nearly every measure of health status. How can this be? What explains this apparent paradox?

The two-part answer is deceptively simple — first, the pathways to better health do not generally depend on better health care, and second, even in those instances in which health care is important, too many Americans do not receive it, receive it too late, or receive poor-quality care. In this lecture, I first summarize where the United States stands in international rankings of health status. Next, using the concept of determinants of premature death as a key measure of health status, I discuss pathways to improvement, emphasizing lessons learned from tobacco control and acknowledging the reality that better health (lower mortality and a higher level of functioning) cannot be achieved without paying greater attention to poor Americans. I conclude with speculations on why we have not focused on improving health in the United States and what it would take to make that happen.

From the Department of Medicine, University of California at San Francisco, San Francisco. Address reprint requests to Dr. Schroeder at the Department of Medicine, University of California at San Francisco, 3333 California St., Suite 430, San Francisco, CA 94143, or at schroeder@medicine.ucsf.edu.

N Engl J Med 2007;357:1221-8.





PERSPECTIVE

MEASURING THE PERFORMANCE OF THE U.S. HEALTH CARE SYSTEM

Ranking 37th — Measuring the Performance of the U.S. Health Care System

Christopher J.L. Murray, M.D., D.Phil., and Julio Frenk, M.D., Ph.D., M.P.H.

Given the vast number of preventable deaths associated with smoking (465,000 per year), hypertension (395,000), obesity (216,000), physical inactivity (191,000), high blood glucose levels (190,000), high levels of low-density lipoprotein cholesterol (113,000), and other dietary risk factors, there are huge opportunities to enact policies that could make a substantial difference in health system performance — and in the population's health.

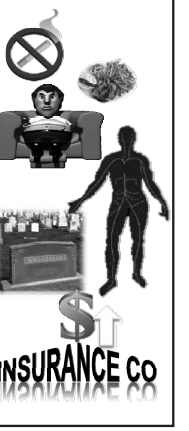
**NEJM 2010; 362:98**

## Beyond Acute and Palliative Care…

- As healthcare providers, we need to become champions of achieving healthy lifestyle overhauls in the patients we serve—well beyond the acute and palliative care provided in our emergency centers, surgical suites, cath labs, hospital rooms, and physician offices.The "paradigm shift" needs to move from not only helping patients when the are ill, injured, or sick, to "helping patients help themselves (24/7) ."
- Helping patients on their path to better health will not only differentiate contemporary primary care physicians as unique healthcare providers, but will move us from the current reactive sick care model to proactive healthcare.

## Outline

- Background/Rationale for Moving to a Proactive Healthcare Model
- Using Emerging Research to Address the Most Proximal or Foundational Risk Factors
- Medications: Addressing Nonadherence and the Associated Adverse Outcomes
- Behavior Change Strategies for the Patient's Immediate Environment



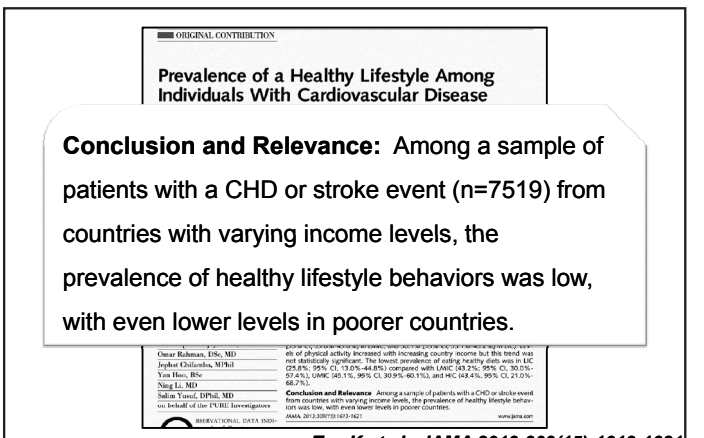

## Telephone Survey

**( 153,000 Adults in the U.S.)**


**Only 3% adhere to 4 healthy lifestyle characteristics, including not smoking, maintaining a normal body weight, eating adequate daily servings of fruits and vegetables, and exercising regularly.**

**Almost 10% of the respondents adhered to none of the practices.**

***Reeves MJ et al. Arch Intern Med 2005;165:854***



ORIGINAL CONTRIBUTION

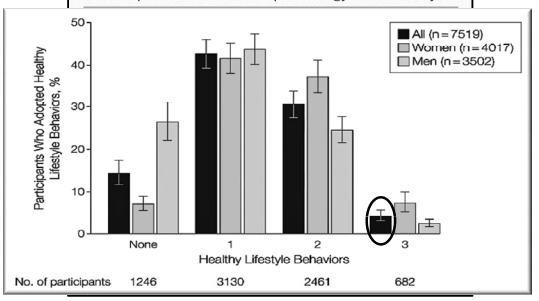
Prevalence of a Healthy Lifestyle Among Individuals With Cardiovascular Disease

**Conclusion and Relevance:** Among a sample of patients with a CHD or stroke event (n=7519) from countries with varying income levels, the prevalence of healthy lifestyle behaviors was low, with even lower levels in poorer countries.

***Teo K et al. JAMA 2013;309(15):1613-1621***

ORIGINAL CONTRIBUTION

**Prevalence of a Healthy Lifestyle Among Individuals With Cardiovascular Disease in High-, Middle- and Low-Income Countries**
The Prospective Urban Rural Epidemiology (PURE) Study




***Teo K et al. JAMA 2013;309(15):1613-1621***

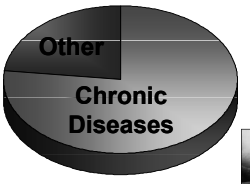
# Health Care Spending

Total health care spending was $2 trillion in 2005, or $6,700 per person, representing 16% of the gross domestic product (GDP). This trend is expected to increase at similar levels over the next few years, reaching $4 trillion or 20% of the GDP.

In other words, health care will account for $1 of every $5 spent in the United States!

Chronic illnesses affect more than a third of working-age Americans and the

Costs associated with chronic diseases account for ~ 75% of the nation's annual health care costs.




**AHA Policy Statement**

**Value of Primordial and Primary Prevention for Cardiovascular Disease**
**A Policy Statement From the American Heart Association**

**The high direct medical care and indirect costs of cardiovascular disease – approaching $450 billion a year in 2010 and projected to rise to over $1.2 trillion a year by 2030 – make this a critical medical and societal issue. Effective prevention strategies are needed if we are to limit the growing burden of cardiovascular disease.**

over $1 trillion a year by 2030—make this a critical medical and societal issue. Prevention of cardiovascular disease will also provide great value in developing a healthier, more productive society. (*Circulation.* 2011;124:967-990.)

Key Words: AHA Scientific Statements ■ cardiovascular diseases ■ prevention

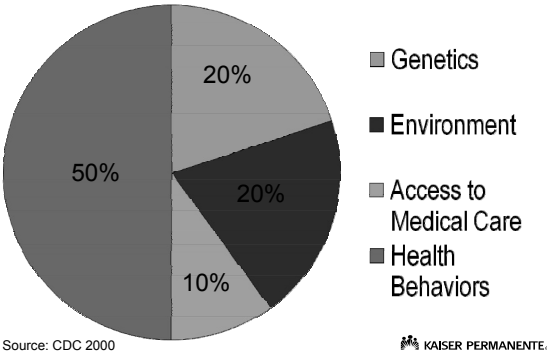
Cardiovascular disease (CVD), including heart disease and stroke, is the leading cause of death and disability in women and men in the United States.[1] The preclinical substrates for clinical CVD (eg, fatty streaks and atherosclerosis) begin early in life and are influenced over time by potentially modifiable risk factors, behaviors, and environmental exposures. Favorable risk factor levels in middle age are associated with a lower lifetime risk for CVD mortality, increased survival, and improved quality of life.[2] Population-based and clinical studies highlight the importance of primordial prevention, defined

**Circulation 2011;124:967-990**

## Outline

- Background/Rationale for Cardiac Rehab and Secondary Prevention
- Using Emerging Research to Address the Most Proximal or Foundational Risk Factors
- Medications: Addressing Nonadherence and the Associated Adverse Outcomes
- Behavior Change Strategies for the Patient's Immediate Environment

**Proportional Contribution to Premature Death**




Source: CDC 2000

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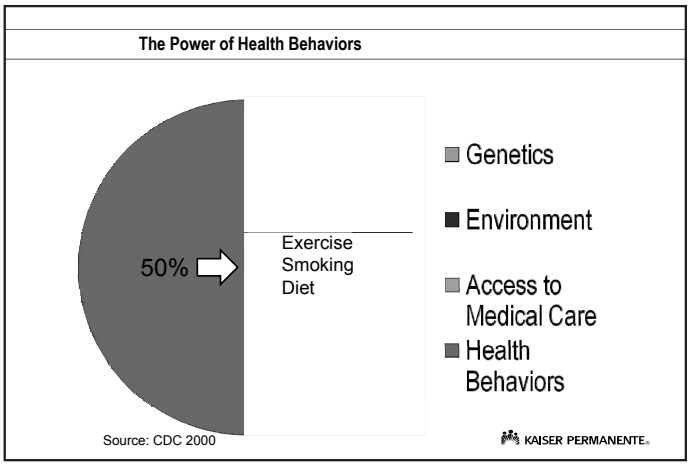
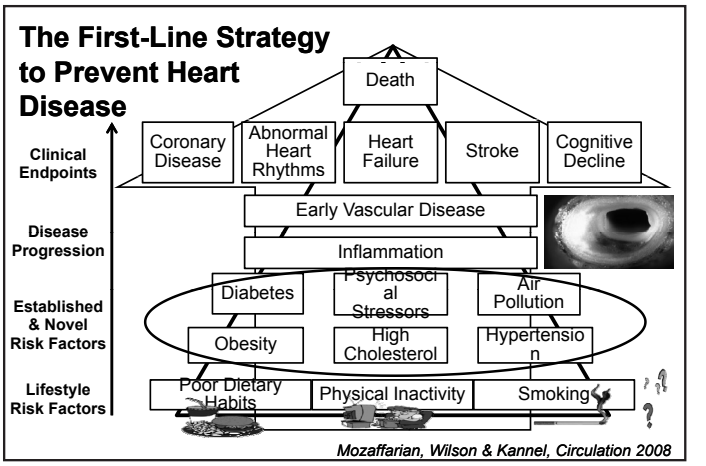
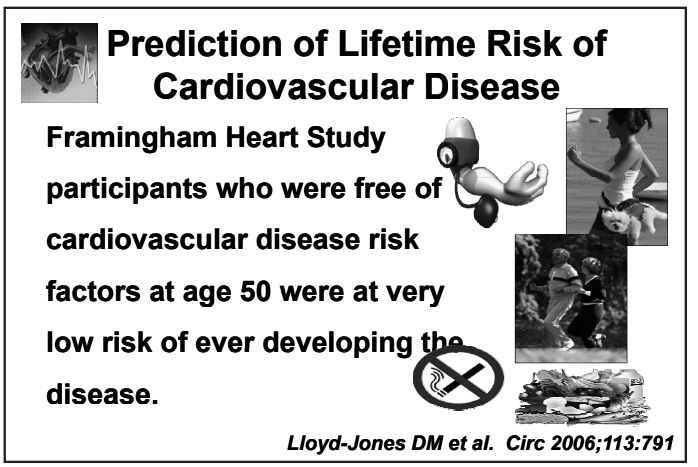
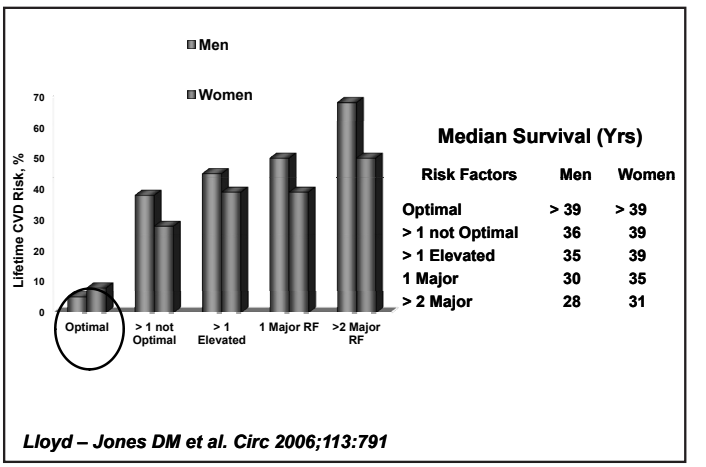
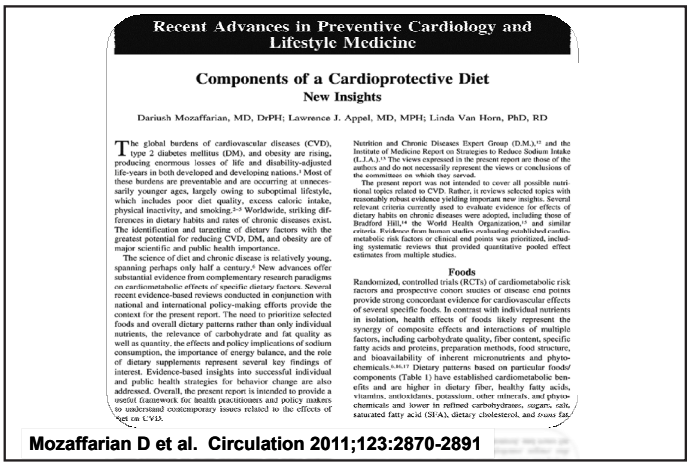
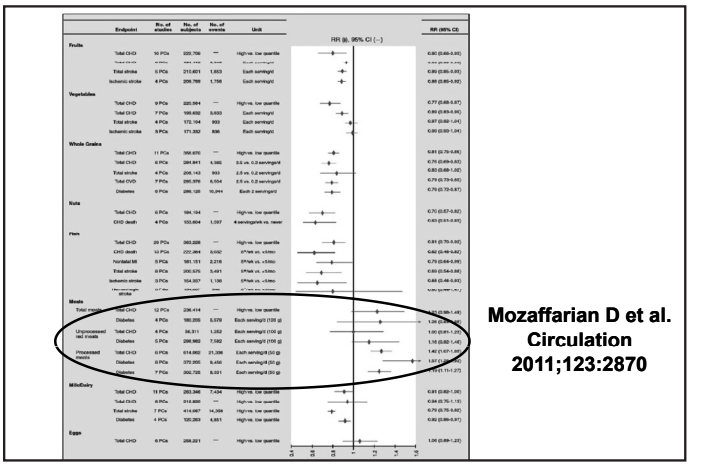

The Power of Health Behaviors
50%
Exercise
Smoking
Diet
Genetics
Environment
Access to Medical Care
Health Behaviors
Source: CDC 2000
KAISER PERMANENTE

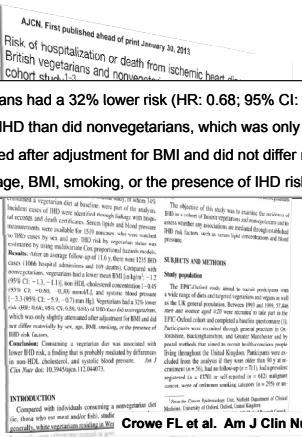

The First-Line Strategy to Prevent Heart Disease
Clinical Endpoints
Disease Progression
Established & Novel Risk Factors
Lifestyle Risk Factors
Death
Coronary Disease
Abnormal Heart Rhythms
Heart Failure
Stroke
Cognitive Decline
Early Vascular Disease
Inflammation
Diabetes
Psychosocial Stressors
Air Pollution
Obesity
High Cholesterol
Hypertension
Poor Dietary Habits
Physical Inactivity
Smoking
Mozaffarian, Wilson & Kannel, Circulation 2008


Prediction of Lifetime Risk of Cardiovascular Disease
Framingham Heart Study participants who were free of cardiovascular disease risk factors at age 50 were at very low risk of ever developing the disease.
Lloyd-Jones DM et al. Circ 2006;113:791


Men
Women
Lifetime CVD Risk, %
70
60
50
40
30
20
10
0
Optimal
> 1 not Optimal
> 1 Elevated
1 Major RF
>2 Major RF
Median Survival (Yrs)
Risk Factors | Men | Women
Optimal | > 39 | > 39
> 1 not Optimal | 36 | 39
> 1 Elevated | 35 | 39
1 Major | 30 | 35
> 2 Major | 28 | 31
Lloyd – Jones DM et al. Circ 2006;113:791


Recent Advances in Preventive Cardiology and Lifestyle Medicine
Components of a Cardioprotective Diet
New Insights
Dariush Mozaffarian, MD, DrPH; Lawrence J. Appel, MD, MPH; Linda Van Horn, PhD, RD
Foods
Mozaffarian D et al. Circulation 2011;123:2870-2891


Mozaffarian D et al. Circulation 2011;123:2870



AJCN. First published ahead of print January 30, 2013

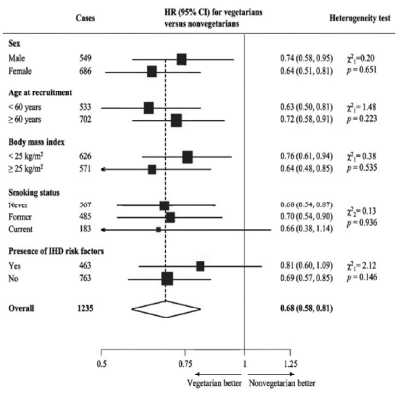
Risk of hospitalization or death from ischemic heart

British vegetarians and nonveg

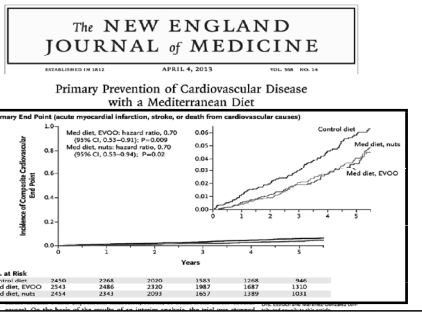
cohort study 1–3

Vegetarians had a 32% lower risk (HR: 0.68; 95% CI: 0.58, 0.81) of IHD than did nonvegetarians, which was only slightly attenuated after adjustment for BMI and did not differ materially by sex, age, BMI, smoking, or the presence of IHD risk factors.

**Crowe FL et al. Am J Clin Nutr 2013; 1-30/2013**




***Crowe FL et al. Am J Clin Nutr 2013; 1-30/2013***



The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 APRIL 4, 2013 VOL. 368 NO. 14

Primary Prevention of Cardiovascular Disease with a Mediterranean Diet

A Primary End Point (acute myocardial infarction, stroke, or death from cardiovascular causes)

Med diet, EVOO: hazard ratio, 0.70 (95% CI, 0.53–0.91); P=0.009
Med diet, nuts: hazard ratio, 0.70 (95% CI, 0.53–0.94); P=0.02

Control diet
Med diet, nuts
Med diet, EVOO

Incidence of Composite Cardiovascular End Point

Years

No. at Risk

| | | | | | | |
|---|---|---|---|---|---|---|
| Control diet | 2450 | 2268 | 2020 | 1583 | 1268 | 946 |
| Med diet, EVOO | 2543 | 2486 | 2320 | 1987 | 1687 | 1310 |
| Med diet, nuts | 2454 | 2343 | 2093 | 1657 | 1389 | 1031 |

Among persons at high cardiovascular risk, a Mediterranean diet supplemented with extra-virgin olive oil or nuts reduced the incidence of major cardiovascular events by ~ 30%.

***Estruch R et al. NEJM 2013;February 25th***

# Dietary Priorities Associated with Cardioprotective Benefits

| Consume more: | Consume less: |
|---|---|
| • Fish and shellfish | • Potatoes, refined grains, sugars |
| • Whole grains | • Processed meats |
| • Fruits | • Sweetened beverages, diet sodas |
| • Vegetables | • Grain-based desserts & bakery goods |
| • Nuts | • Fats, oil or foods containing partially hydrogenated vegetable oils |
| • Low-fat or no fat diary products | • Salt |
| • Vegetable oils* | • Alcohol** |
| • Water | |

* Examples include flaxseed, canola, and soybean oil

** For adults who drink alcohol, no more than moderate consumption (i.e., up to 2 drinks/day for men, 1 drink/day for women) should be encouraged, ideally with meals.

AHA Presidential Advisory

**The Importance of Population-Wide Sodium Reduction as a Means to Prevent Cardiovascular Disease and Stroke**

**A Call to Action From the American Heart Association**

Lawrence J. Appel, MD, MPH, FAHA; Edward D. Frohlich, MD, FAHA; John E. Hall, PhD, FAHA; Thomas A. Pearson, MD, PhD, FAHA; Ralph L. Sacco, MD, FAHA; Douglas R. Seals, PhD; Frank M. Sacks, MD, FAHA; Sidney C. Smith, Jr, MD, FAHA; Dorothea K. Vafiadis, MS; Linda V. Van Horn, PhD, RD, FAHA

Blood pressure (BP)–related diseases, specifically, stroke, coronary heart disease, heart failure, and kidney disease, are leading causes of morbidity and mortality in the United States and throughout the world. In the United States, coronary heart disease and stroke are the leading causes of mortality, whereas heart failure is the leading cause of hospitalizations.[1] Concurrently, the prevalence of chronic kidney disease remains high and is escalating.[2,3] The direct and indirect costs of these conditions are staggering, over $400 billion just for cardiovascular disease (CVD) in 2009.[3,4] The human consequences are likewise enormous.

The relation between BP and adverse health outcomes is direct and progressive with no evidence of a threshold, that is, the risk of CVD, stroke, and end-stage kidney disease increases progressively throughout the range of usual BP starting at a level of ~115/75 mm Hg.[5–7] Overall, elevated BP is the second leading modifiable cause of death, accounting for an estimated 395 000 preventable deaths in the United States in 2005.[8] Worldwide, elevated BP accounts for 54% of stroke and 47% of coronary heart disease events; importantly, about half of these events occur in persons without hypertension.[9]

The 2020 goal of the American Heart Association (AHA) is to improve the cardiovascular health of the United States by 20% while continuing to reduce deaths from CVD and stroke by 20%.[4] Two of the key metrics for ideal cardiovascular health are a BP of <120/80 mm Hg and sodium consumption of <1500 mg/d. The purpose of this advisory is 2-fold: first, to highlight the impressive body of evidence that links sodium intake with elevated BP and other adverse outcomes, and second, to serve as a call to action on behalf of the AHA for individuals, healthcare providers, professional organizations, governments, and industry to address this major public health issue. See Table for key points.

**The Evidence**

Excess intake of salt (sodium chloride) has a major role in the pathogenesis of elevated BP. Excess sodium intake also has BP-independent effects, promoting left ventricular hypertrophy as well as fibrosis in the heart, kidneys, and arteries.[10] Evidence on the adverse health effects of excess sodium intake includes results from animal studies, epidemiological studies, clinical trials, and meta-analyses of trials.[11] To date, >50 randomized trials have tested the effects of sodium reduction on BP in adults. A meta-analysis[12] of these trials documented that a median reduction in urinary sodium of ~1800 mg/d between 4 and 6 g/d reduced BP by 2.0/1.0 mm Hg in nonhypertensive individuals and by 5.0/2.7 mm Hg in hypertensive individuals. In a subsequent meta-analysis of trials in children, a reduced sodium intake lowered mean systolic/diastolic BP by 1.2/1.3 mm Hg in children and adolescents and lowered systolic BP by 2.5 mm Hg in infants.[13] The benefits of sodium reduction in persons with overt or nonhypertensive BP are substantiated in trial of patients with resistant hypertension, reducing sodium intake by 4600 mg/d lowered systolic/diastolic BP by 22.7/9.1 mm Hg.[14]

Some of the most persuasive evidence on the effects of sodium on BP comes from rigorously controlled, dose-response trials.[15–17] Each of these trials tested at least 3 sodium levels, and each documented statistically significant, direct, progressive, dose-response relations. The lowest level of sodium intake in

**Circulation 2011;123:00-00**



Embargoed for release: Monday, Feb. 11, 2013, 3 p.m. CT/4 p.m. ET

**Epidemiology/Population Science**

**Mortality Benefits From US Population-wide Reduction in Sodium Consumption**

A gradual reduction in dietary sodium over the next decade as might be achieved with a range of proposed public health interventions would yield considerable health benefits, with mean effects ranging from 280,000 to 500,000 deaths averted.

population-wide mean of 2200 mg/d; and scenario C, instantaneous reduction to 1500 mg sodium per day sustained for 10 years. All 3 methods consistently show a substantial health benefit for reductions in dietary sodium under each of the 3 scenarios tested. A gradual reduction in dietary sodium over the next decade (scenario A) as might be achieved with a range of proposed public health interventions would yield considerable health benefits over the next decade, with mean effects across the 3 models ranging from 280 000 to 500 000 deaths averted. Projections of instantaneous reductions illustrate the maximum benefits that could be achieved (0.7–1.2 million deaths averted in 10 years). Under 3 different modeling assumptions, the projected health benefits from reductions in dietary sodium are substantial. (***Hypertension. 2013;61:564-570.***) ● **Online Data Supplement**

**Key Words:** cardiovascular diseases ■ computer simulation ■ dietary sodium ■ hypertension ■ mortality

***Hypertension 2013;61:564-570***

VIEWPOINT

## Changing Eating Habits for the Medical Profession

Leonard I. Lesser, MD, MSHS
Deborah A. Cohen, MD, MPH
Robert H. Brook, MD, ScD

DO TO PROFESSIONALS SPEND A GREAT DEAL OF THEIR at meetings. Grand rounds, noon seminars, to-

Research has shown that there are too many calories in the food served at children's hospitals and academic medical centers.[1] Food served at medical meetings does not seem to adhere to any nutritional guidelines,[2] but as patients are advised to increase their consumption of fruits, vegetables, and whole grains, it is time to incorporate this advice into meals served in health care settings, as health care profes-

gues of 9 SI. Overweight physicians may have an effect on patient care, because overweight physicians are less likely to counsel patients about obesity.[3]

The Institute of Medicine recently recommended that health care professionals should act "as role models for their patients and provide] leadership for obesity prevention efforts in their communities by advocating for institutional, community, and state-level strategies that can improve physical activity and nutrition outcomes for those patients on lifestyle communication."[4] Yet there has been little change in the food provided to health professionals, which is paid for by health care dollars.

sions, meeting organizers could require calorie labeling, with an indication as to whether the food item has more or less than the recommended calories. Sugar-sweetened beverages could be replaced with nonnutritive drinks. Desserts and snacks could be made available in 100-calorie or smaller "bite-ing" portions.

Author Affiliations: Yale Alta Medical Journalism Research Institute, Palo Alto, California (L. Lesser); Yale University School of Medicine, New Haven, Connecticut (L. Lesser); Department of Family Medicine, David Geffen School of Medicine at UCLA, Los Angeles (D. Cohen); RAND Corporation, Santa Monica, California (R. Brook).
Corresponding Author: Leonard I. Lesser, MD, MSHS, Health Policy, Palo Alto Medical Foundation Research Institute, 795 El Camino Real Annex Bldg, Palo Alto, CA 94304 (lesser1@yahoo.com).

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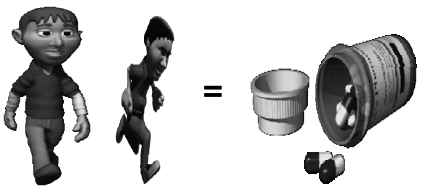
JAMA, September 12, 2012—Vol 308, No. 10 983

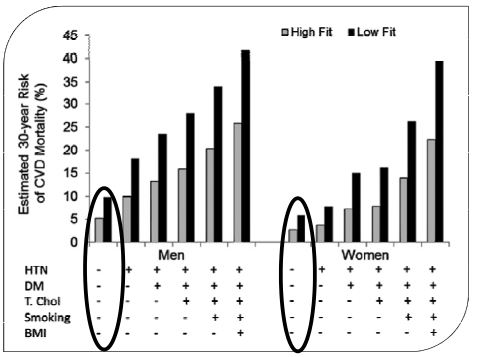
The medical profession was influential in reducing smoking in the U.S.; it has the capacity to encourage food-system change (and physical activity) within its own institutions. This would likely reduce caloric consumption of health professionals, promote the health of physicians, and could also cause a ripple effect in local food economies. It may also favorably impact the patients we care for and treat on a day-to-day basis.

*Lesser LI et al. JAMA 2012;308:983*

**If there was a pill that you could take to cut your risk in HALF of dying from heart disease over the next 30 years, would you take it ? There is such a pill---and its called EXERCISE.**



**Regardless of the Risk Factor Profile, Low Fit Men and Women have ~ 2x the Mortality**




*Wickramasinghe CD et al. Circ Cardiovasc Qual Outcomes 2014 (lifetimerisk.org)*

## Papers

### Mortality in relation to smoking: 50 years' observations on male British doctors

Richard Doll, Richard Peto, Jillian Boreham, Isabelle Sutherland

**Abstract**

**Objective** To compare the hazards of cigarette smoking in men who formed their habits at different periods, and the extent of the reduction in risk when cigarette smoking is stopped at different ages.
**Design** Prospective study that has continued from 1951 to 2001.
**Setting** United Kingdom.
**Participants** 34 439 male British doctors. Information about their smoking habits was obtained in 1951, and periodically thereafter; cause specific mortality was monitored for 50 years.
**Main outcome measures** Overall mortality by smoking habit, considering separately men born in different periods.
**Results** The excess mortality associated with smoking chiefly involved vascular, neoplastic, and respiratory diseases that can be caused by smoking. Men born in 1900-1930 who smoked only cigarettes and continued smoking died on average about 10 years younger than lifelong non-smokers. Cessation at age 60, 50, 40, or 30 years gained, respectively, about 3, 6, 9, or 10 years of life expectancy. The excess mortality

**Introduction**

During the 19th century much tobacco was smoked in pipes or as cigars and little was smoked as cigarettes, but during the first few decades of the 20th century the consumption of manufactured cigarettes increased greatly.[1] This led eventually to a rapid increase in male lung cancer, particularly in the United Kingdom (where the disease became by the 1940s a major cause of death). Throughout the first half of the 20th century the hazards of smoking had remained largely unsuspected.[1] Around the middle of the century, however, several case-control studies of lung cancer were published in Western Europe[2-5] and North America,[6-10] leading to the conclusion in 1950 that smoking was "a cause, and an important cause" of the disease.[1]

**1951 prospective study**

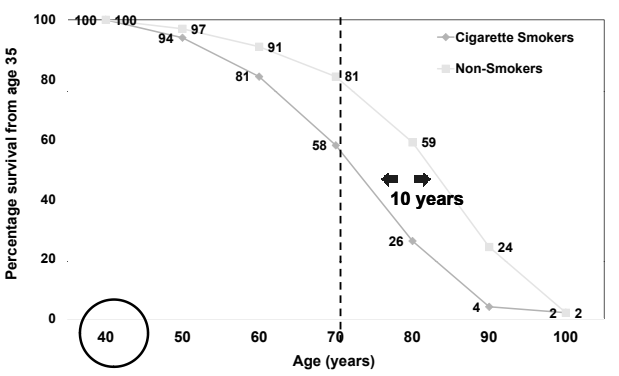
This discovery stimulated much further research into the effects of smoking (not only on lung cancer but also on many other diseases), including a UK prospective study of smoking and death among British doctors that began in 1951 and has now continued for 50 years.[11-17] The decision that this study would be conducted

*Editorial by*

Clinical Trial Service Unit and Epidemiological Studies Unit (CTSU), Radcliffe Infirmary, Oxford OX2 6HE
Richard Doll *emeritus professor of medicine*
Richard Peto *professor of medical statistics and epidemiology*
Jillian Boreham *senior research fellow*
Isabelle Sutherland *research assistant*
Correspondence to: R Doll
secretary@ctsu.ox.ac.uk

*BMJ* 2004;328:1519–33

**BMJ 2004;328:1519**




**BMJ 2004;328:1519**

SPECIAL ARTICLE

## 21st-Century Hazards of Smoking and Benefits of Cessation in the United States

Prabhat Jha, M.D., Chinthanie Ramasundarahettige, M.Sc., Victoria Landsman, Ph.D., Brian Rostron, Ph.D., Michael Thun, M.D., Robert N. Anderson, Ph.D., Tim McAfee, M.D., and Richard Peto, F.R.S.

ABSTRACT

BACKGROUND

Extrapolation from studies in the 1980s suggests that smoking causes 25% of deaths among women and men 35 to 69 years of age in the United States. Nation-

From the Center for Global Health Research, Toronto (PJ), CA. V.L.; the Food

N Engl J Med 2013;368:341–50

Life expectancy was shortened by ~ 11-12 years among the current smokers, as compared with those who had never smoked.

Cessation before the age of 40 years reduced the risk of death associated with continued smoking by about 90%.

had never smoked. Adults who had quit smoking at 25 to 34, 35 to 44, or 45 to 54 years of age gained about 10, 9, and 6 years of life, respectively, as compared with those who continued to smoke.

CONCLUSIONS

Smokers lose at least one decade of life expectancy, as compared with those who have never smoked. Cessation before the age of 40 years reduces the risk of death associated with continued smoking by about 90%.

*Prabhat Jha et al. NEJM 2013;368:341*



**Changes in Ambulance Calls After Implementation of a**

Initial implementation of the smoke-free law (which exempted casinos) was followed by a significant 22.8% drop in ambulance calls from locations other than casinos, but no significant change in calls from casinos. The law requiring smoke-free casinos taking effect was followed by a 19.1% drop in ambulance calls from casinos, but no change in calls originating outside casinos.

from casinos (but not calls from elsewhere) when the law was extended to casinos, suggests that the important effects of secondhand smoke exposure occur acutely. These results also suggest that exempting casinos from smoke-free laws means that more people will suffer medical emergencies. (*Circulation*. 2013;128:811-813.)

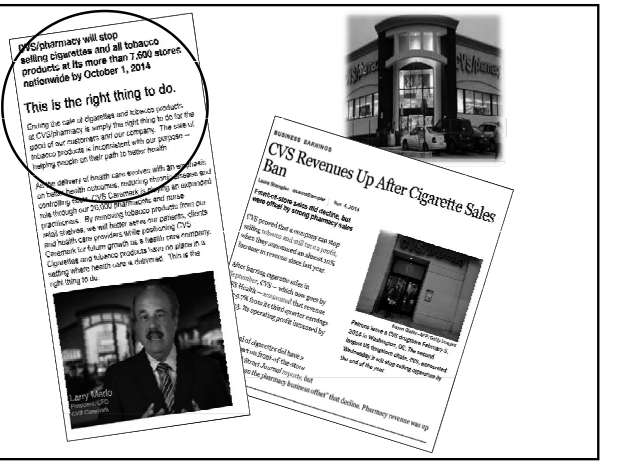
**Key Words:** cardiovascular diseases ■ emergency medical services ■ public policy ■ risk factors ■ smoking ■ tobacco smoke pollution ■ utilization

There is strong and consistent scientific evidence that there are drops in hospital admissions for acute myocardial infarction, other cardiac events, stroke, asthma, and other pulmonary events after implementation of smoke-free laws,[1] with stronger laws being associated with bigger effects.[2] This benefit is stable over time,[2] still persistent 4

followed by changes in ambulance calls originating from the general public and from casinos.

**Editorial see p 783**
**Clinical Perspective on p 813**

***Glantz SA et al. Circulation 2013;128:811-813***




## Outline

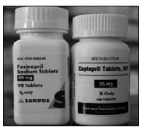
- Background/Rationale for Cardiac Rehab and Secondary Prevention
- Using Emerging Research to Address the Most Proximal or Foundational Risk Factors
- Medications: Addressing Nonadherence and the Associated Adverse Outcomes
- Behavior Change Strategies for the Patient's Immediate Environment

# Cardioprotective Medications*


**Aspirin (162 mg/d)+**

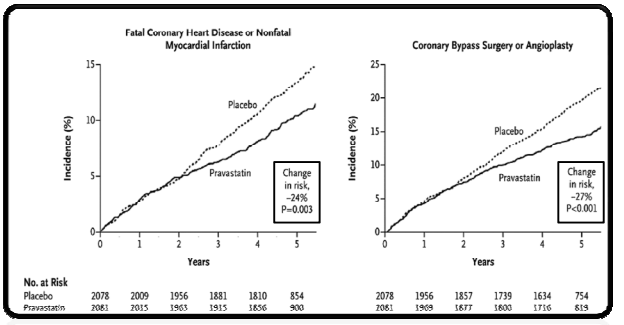
**Statin (Cholesterol Lowering)**

**Beta- blockers (Post MI, LV dysfunction)**

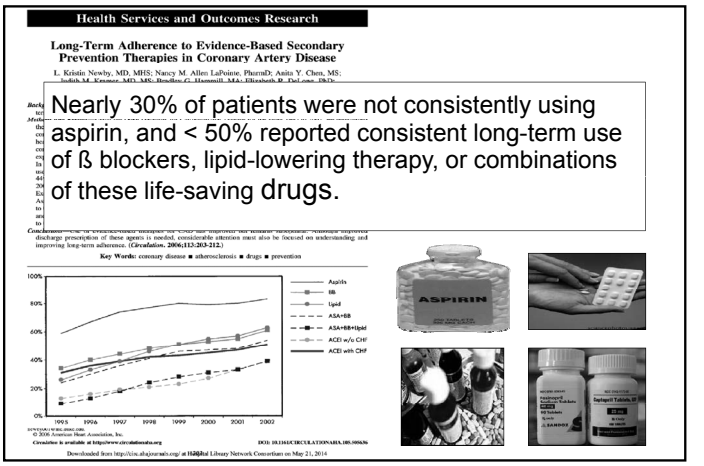


**ACE-I or ARB (EF ≤ 40%, DM, HTN)**

***18 - 44% Risk Reduction (Median, 23 %) ; + Dalen, JE. Am J Med 2010; 123; 101.**




*Sacks FM et al. NEJM 1996;335:1001*



**Health Services and Outcomes Research**

**Long-Term Adherence to Evidence-Based Secondary Prevention Therapies in Coronary Artery Disease**

L. Kristin Newby, MD, MHS; Nancy M. Allen LaPointe, PharmD; Anita Y. Chen, MS; Judith M. Kramer, MD, MSc; Bradley G. Hasselblad, MA; Elizabeth R. DeLong, DSc;

Nearly 30% of patients were not consistently using aspirin, and < 50% reported consistent long-term use of ß blockers, lipid-lowering therapy, or combinations of these life-saving drugs.

**Key Words:** coronary disease ■ atherosclerosis ■ drugs ■ prevention

**Medication nonadherence is associated with a broad range of adverse outcomes in patients with coronary artery disease**

In multivariate analysis, nonadherence remained significantly associated with increased all-cause mortality risk for ß blockers (hazard ratio [HR] 1.50, 95% CI 1.33 – 1.71), ACE inhibitors (HR 1.74, 95% CI 1.52 – 1.98), and statins (HR 1.85, 95% CI 1.63 – 2.09).

These findings suggest that medication nonadherence should be a target for quality improvement interventions to maximize the outcomes of patients with coronary artery disease.

statin medications. Multivariable Cox regression assessed the association between medication nonadherence as a time-

cardiovascular mortality for β-blockers (HR 1.53, 95% CI 1.16-2.01), ACE inhibitors (HR 1.66, 95% CI 1.26-2.20), and statins (HR 1.62, 95% CI 1.124-2.13). The findings of increased risk associated with nonadherence were consistent for cardiovascular hospitalization and revascularization procedures.

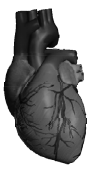
**Conclusions** Nonadherence to cardioprotective medications is common in clinical practice and associated with a broad range of adverse outcomes. These findings suggest that medication nonadherence should be a target for quality improvement interventions to maximize the outcomes of patients with CAD. (Am Heart J 2008;155:772-9.)

Clinical trials have demonstrated the efficacy of β-blockers, angiotensin-converting enzyme (ACE) inhi- patients with CAD to reduce recurrent cardiovascular events.[1] Accordingly, national quality improvement

*Ho P M et al. Am Heart J 2008;155:772-9*

**Cardioprotective Benefits of Lowering Resting Heart Rate & Blood Pressure ?**

In conclusion, in post-MI pts, this meta-regression of randomized clinical trials robustly suggests that the benefit of drugs modifying HR is strongly related to the magnitude of reduction in resting HR.



Each 10 bpm reduction in resting HR is estimated to reduce the relative risk of cardiac death by about 30%.

*Tenormin*
*Lopressor*
*Toprol-XL*
*Inderal*

*Cucherat M. Eur Heart J 2007;28:3012*

THE NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

We randomly assigned 9361 persons with a systolic blood pressure of 130 mm Hg or higher and an increased cardiovascular risk, but without diabetes, to a systolic blood-pressure target of less than 120 mm Hg (intensive treatment) or a target of less than 140 mm Hg (standard treatment).

The intervention was stopped early after a median follow-up of 3.26 years owing to a significantly lower rate of the primary composite outcome in the intensive-treatment group than in the standard-treatment group (1.65% per year vs 2.19% per year; hazard ratio with intensive treatment, 0.75; 95% CI, 0.64 to 0.89; p<0.001).

injury or fibrosis, but not of injurious falls, were higher in the intensive-treatment group than in the standard-treatment group.

CONCLUSIONS

Among persons at high risk for cardiovascular events but without diabetes, targeting a systolic blood pressure of less than 120 mm Hg, as compared with less than 140 mm Hg, resulted in lower rates of fatal and nonfatal major cardiovascular events and death from any cause, although significantly higher rates of some adverse events were observed in the intensive-treatment group. (Funded by the National Institutes of Health; ClinicalTrials.gov number, NCT01206022.)

The New England Journal of Medicine

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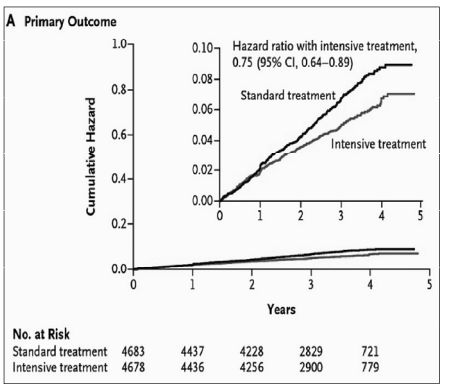


*This article was published on Nov. 9, 2015 at NEJM.org*

A strategy to reduce cardiovascular disease by more than 80%

N J Wald, M R Law

Abstract

**Objectives** To determine the combination of drugs and vitamins, and their doses, for use in a single daily pill to achieve a large effect in preventing cardiovascular disease with minimal adverse effects. The strategy was to simultaneously reduce four cardiovascular risk factors (low density lipoprotein cholesterol, blood pressure, serum homocysteine, and platelet function) regardless of pretreatment levels. **Design** We quantified the efficacy and adverse effects of the proposed formulation from published meta-analyses of randomised trials and cohort studies and a meta-analysis of 15 trials of low dose (50-125 mg/day) aspirin. **Outcome measures** Proportional reduction in ischaemic heart disease (IHD) events and strokes; life years gained; and prevalence of adverse effects. **Results** The formulation which met our objectives was: a statin (for example, atorvastatin (daily dose 10 mg) or simvastatin (40 mg)); three blood pressure lowering drugs (for example, a thiazide, a β blocker, and an angiotensin converting enzyme inhibitor),

the diseases common. Cardiovascular disease can be avoided or delayed, but the necessary changes in Western diet and lifestyle are not practicable in the short term. Randomised trials show that drugs to lower three risk factors—low density lipoprotein (LDL) cholesterol,[1] blood pressure,[2a] and platelet function (with aspirin)[3]—reduce the incidence of ischaemic heart disease (IHD) events and stroke. Evidence that lowering serum homocysteine (with folic acid) reduces the risk of these diseases is largely observational but still compelling.[4-10]

Drug treatment to prevent IHD events and stroke has generally been limited to single risk factors, to targeting the minority of patients with values in the tail of the risk factor distribution, and to reducing the risk factors to "average" population values. This policy can achieve only modest reductions in disease.[11] A large preventive effect would require intervention in everyone at increased risk irrespective of the risk factor levels; intervention on several reversible causal risk factors together; and reducing these risk factors by as much as possible.[12]

We describe a system to prevent cardiovascular

Editorials by Rodgers

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N J Wald *professor*

M R Law *professor*

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bmj.com 2003;326:1419

VIEWPOINT

ONLINE FIRST

**Combination Therapy to Prevent Cardiovascular Disease**

Slow Progress

The concept of combining antihypertensive drugs, a statin, and aspirin into a single, fixed-dose, combination pill to prevent myocardial infarction and stroke is now a dozen years old.

each pill is licensed in most countries.

Only a small proportion—perhaps fewer than 10%—of individuals in the world who have, or are at high risk of developing, cardiovascular disease receive preventive therapy.

will meet trials with clinical outcomes to consider a combination pill for use in primary prevention. At least 2 large international trials (TIPS-3 and HOPE-3) are currently under way to evaluate a combination will use in a general setting

At least 6 randomized trials have shown that the combination of several antihypertensive agents, a statin, and aspirin can substantially reduce blood pressure and lipid levels and, when aspirin is included, inhibit platelet aggregation. The pills are well tolerated and have low rates of adverse effects and discontinuation.

discuss the risk of cardiovascular disease into a single pill could increase use of effective and inexpensive medications, thereby lowering cost and improving treatment adherence. In most low- and middle-income countries it will also be necessary to strengthen health systems with systematic screening and follow-up through greater use of nonphysician health workers and innovative and simple communication technologies.

Different fixed-dose combination pills are now available in India, Mexico, and Cuba and South America. At least

or 5 drugs. An emerging opinion among researchers and some regulators is that outcome studies are not needed for polypill use (called for licensing of fixed-dose combination pills for secondary prevention as long as the expected effects on

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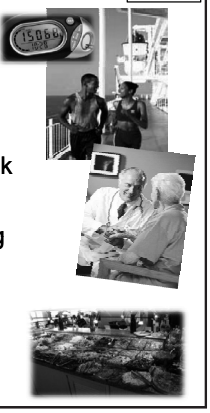
JAMA 2013;309 (15):1595

## Outline

- Background/Rationale for Cardiac Rehab and Secondary Prevention
- Using Emerging Research to Address the Most Proximal or Foundational Risk Factors
- Medications: Addressing Underdosing and Poor Compliance
- Behavior Change Strategies for the Patient's Immediate Environment





The NEW ENGLAND JOURNAL of MEDICINE

Perspective

JULY 5, 2012

**Automated Hovering in Health Care — Watching Over the 5000 Hours**

David A. Asch, M.D., M.B.A., Ralph W. Muller, M.A., and Kevin G. Volpp, M.D., Ph.D.

The dominant form of health care financing in the United States supports a reactive, visit-based model in which patients are seen when they become ill, typically during hospitalizations and at outpatient visits. That care model falls short not just because it is expensive and often fails to proactively improve health, but also because so much of health is explained by individual behaviors, most of which occur outside health care encounters. Indeed, even patients with chronic illness might spend only a few hours a year with a doctor or nurse, but they spend 5000 waking hours each year engaged in everything else — including deciding whether to take prescribed medications or follow other medical advice, deciding what to eat and drink and whether to smoke, and making other choices about activities that can profoundly affect their health.

The increasing attention being paid to those 5000 hours takes various forms. Employers are focusing more on employees' wellness — how they eat, whether they smoke, and how much they exercise. Medication adherence has become a more important goal, thanks to growing recognition that many people with chronic conditions fail to take their medications regularly and therefore do not get the benefits that health care can provide. Home-based biometric assessments of indicators such as glucose level, blood pressure, and weight are emerging as part of longitudinal clinical care. Transitional care models are being touted as a way of coordinating care beyond hospitalization. And hospitals and health plans are developing "hot-spotter" approaches, deploying tailored and intensive attention to managing the care of their most challenging patients.[3] All three activities occur outside the conventional, billable, clinical encounter — and all reflect some sort of hovering over people in their daily lives.

Conventional approaches to improving patient engagement along these dimensions have been personal-intensive — using visiting nurses or clinically staffed telemedicine services. Although results have been mixed, in general these programs have not fulfilled their promise. One problem is that using personnel in hovering is expensive and therefore difficult to scale up and to justify, except for the very sickest patients, some of whom might be too sick to benefit. Another problem is

**From Sick Care to Health Care — Reengineering Prevention into the U.S. System**

Farshad Fani Marvasti, M.D., M.P.H., and Randall S. Stafford, M.D., Ph.D.

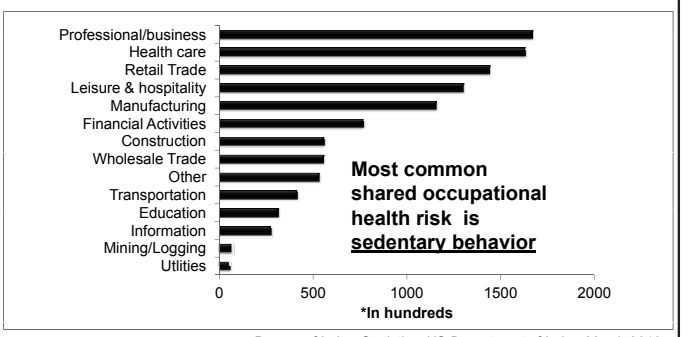
Although the United States spends more for medical care than any other country, problems abound in our health care system. Unsustainable costs, poor outcomes, frequent medical errors, poor patient satisfaction, and worsening health disparities all point to a need for transformative change.[1] Simultaneously, we face widening epidemics of obesity and chronic disease. Cardiovascular disease, cancer, and diabetes now cause 70% of U.S. deaths and account for nearly 75% of health care expenditures.[2] Unfortunately, many modifiable risk factors for chronic diseases are not being addressed adequately. A prevention model, focused on forestalling the development of disease before symptoms or life-threatening events occur, is the best solution to the current crisis.

Disease prevention encompasses all efforts to anticipate the genesis of disease and forestall its progression to clinical manifestations. A focus on prevention does not imply that disease can be eliminated but instead embraces Feinstein's model of "modifi-

The dominant form of health care financing in the U.S. supports a reactive visit-based model in which patients are seen when they become ill, typically during hospitalizations and at outpatient visits. That care model falls short not just because it is expensive and often fails to proactively improve health, but also because so much of health is explained by individual behaviors, most of which occur outside health care encounters (5,000+ waking hours each year).

A prevention model, focused on forestalling the development of disease before symptoms or life-threatening events occur, is the best solution to the current crisis.

## Providing Interventions Where People Spend their Time ?




*Bureau of Labor Statistics, US Department of Labor March 2010*
*www.bls.gov.nnews.release/empsit.t17.htm*

## Rationale for Worksite Wellness?

Because individuals with chronic disease typically spend ~ 5000+ hours each year outside of medical providers*, it is critical to connect them with health-promoting resources in their immediate environment.

- **Universities**

- **Worksite Wellness (10:10:10)**

- **Community Resources**

- **Prevention-Focused Hospitals**

**AHA Scientific Statement**

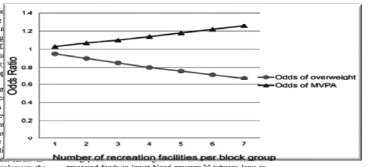
**American Heart Association Guide for Improving Cardiovascular Health at the Community Level, 2013 Update**

**A Scientific Statement for Public Health Practitioners, Healthcare Providers, and Health Policy Makers**

Thomas A. Pearson, MD, PhD, FAHA, Co-Chair; Latha P. Palaniappan, MD, MS, FAHA, Co-Chair; Nancy T. Artinian, PhD, RN, FAHA; Mercedes R. Carnethon, PhD, FAHA; Michael H. Criqui, MD, MPH, FAHA; Stephen R. Daniels, MD, PhD, FAHA; Gregg C. Fonarow, MD, PhD, FAHA; Stephen P. Fortmann, MD; Barry A. Franklin, PhD, FAHA; James M. Galloway, MD, FAHA; David C. Goff, Jr., MD, PhD, FAHA; Gregory W. Heath, DHSc, MPH, FAHA; Ariel T. Holland Frank; Penny M. Kris-Etherton, PhD, RD; Darwin R. Labarthe, MD, MPH, PhD, FAHA; Joanne M. Murabito, MD, ScM; Ralph L. Sacco, MD, MS, FAHA; Comilla Sasson, MD, MS; Melanie B. Turner, MPH; on behalf of the American Heart Association Council on Epidemiology and Prevention

The goal of this American Heart Association Improving Cardiovascular Health at the Level (AHA Community Guide) is to provide sive inventory of evidence-based goals, strateg ommendations for cardiovascular disease (CVD prevention that can be implemented on a com This guide advances the 2003 AHA Communit the 2005 AHA statement on guidance for imp by incorporating new evidence for community gained over the past decade, expanding the tar to include a broader range of community advoc with the concepts and terminology of the AHA Goals, and recognizing the contributions of ne private sector programs involving community in

In recent years, expanding arrays of programs have been implemented in increasingly diverse to provide tools, strategies, and other best practi tially reduce the incidence of initial and recurre cular events. The AHA Community Guide complements the AHA statement entitled "Population Approaches to Improve




processed foods to lower blood pressure,[7,8] tobacco taxes to promote smoking cessation,[9–11] and modification of the built

The opinions expressed in this paper are those of the authors and do not necessarily reflect the views of the Office of the US Department of Health and Human Services or the Federal Government.

The American Heart Association makes every effort to avoid any actual or potential conflicts of interest that may arise as a result of an outside relationship or a personal, professional, or business interest of a member of the writing panel. Specifically, all members of the writing group are required to complete and submit a Disclosure Questionnaire showing all such relationships that might be perceived as real or potential conflicts of interest.

This statement was approved by the American Heart Association Science Advisory and Coordinating Committee on January 18, 2013. A copy of the document is available at http://my.americanheart.org/statements by selecting either the "By Topic" link or the "By Publication Date" link. To purchase

*Pearson TA et al. Circulation 2013; 127:1730-1733*

REVIEW — CLINICIAN'S CORNER

**Using Pedometers to Increase Physical Activity and Improve Health**

A Systematic Review

Dena M. Bravata, MD, MS
Crystal Smith-Spangler, MD
Vandana Sundaram, MPH
Allison L. Gienger, BA
Nancy Lin, ScD
Robyn Lewis, MA
Christopher D. Stave, MLS
Ingram Olkin, PhD
John R. Sirard, PhD

**Context** Without detailed evidence of their effectiveness, pedometers have recently become popular as a tool for motivating physical activity.

**Objective** To evaluate the association of pedometer use with physical activity and health outcomes among outpatient adults.

**Data Sources** English-language articles from MEDLINE, EMBASE, Sport Discus, PsycINFO, Cochrane Library, Thompson Scientific (formerly known as Thompson ISI), and ERIC (1966-2007); bibliographies of retrieved articles; and conference proceedings.

**Study Selection** Studies were eligible for inclusion if they reported an assessment of pedometer use among adult outpatients, reported a change in steps per day, and included more than 5 participants.

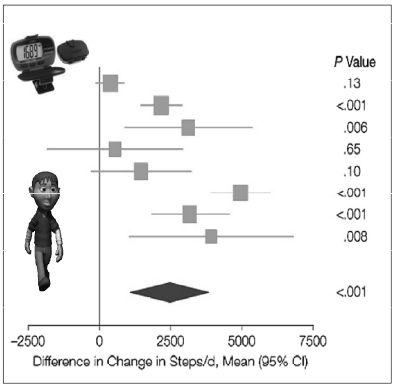
**Data Extraction and Data Synthesis** Two investigators independently abstracted data about the intervention; participants; number of steps per day; and presence or absence of obesity, diabetes, hypertension, or hyperlipidemia. Data were pooled using random-effects calculations, and meta-regression was performed.

**Results** Our searches identified 2246 citations; 26 studies with a total of 2767 participants met inclusion criteria (8 randomized controlled trials [RCTs] and 18 observational studies). The participants' mean (SD) age was 49 (9) years and 85% were women. The mean intervention duration was 18 weeks. In the RCTs, pedometer users significantly increased their physical activity by 2491 steps per day more than control participants (95% confidence interval [CI], 1098-3885 steps per day, $P < .001$). Among the observational studies, pedometer users significantly increased their physical activity by 2183 steps per day over baseline (95% CI, 1571-2796 steps per day, $P < .0001$). Overall, pedometer users increased their physical activity by 26.9% over baseline. An important predictor of increased physical activity was having a step goal such as 10 000 steps per day ($P = .001$). When data from all studies were combined, pedometer users significantly decreased their body mass index by 0.38 (95% CI, 0.05-0.72; $P = .03$). This decrease was associated with older age ($P = .001$) and having a step goal ($P = .04$). Intervention participants significantly decreased their systolic blood pressure by 3.8 mm Hg (95% CI, 1.7-5.9 mm Hg, $P < .001$). This decrease was associated with greater baseline systolic blood pressure ($P = .009$) and change in steps per day ($P = .08$).

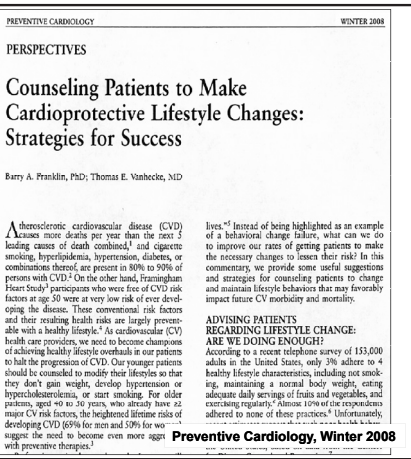
**Conclusions** The results suggest that the use of a pedometer is associated with significant increases in physical activity and significant decreases in body mass index and blood pressure. Whether these changes are durable over the long term is undetermined.

*JAMA. 2007;298(19):2296-2304* www.jama.com

***JAMA 2007;298(19):2296-2304***




*Bravata DM et al. JAMA 2007;298(19):2296*


PREVENTIVE CARDIOLOGY WINTER 2008

PERSPECTIVES

Counseling Patients to Make Cardioprotective Lifestyle Changes: Strategies for Success

Barry A. Franklin, PhD; Thomas E. Vanhecke, MD

Atherosclerotic cardiovascular disease (CVD) causes more deaths per year than the next 3 leading causes of death combined,[1] and cigarette smoking, hyperlipidemia, hypertension, diabetes, or combinations thereof, are present in 80% to 90% of persons with CVD.[2] On the other hand, Framingham Heart Study[3] participants who were free of CVD risk factors at age 50 were at very low risk of ever developing the disease. These conventional risk factors and their resulting health risks are largely preventable with a healthy lifestyle.[4] As cardiovascular (CV) health care providers, we need to become champions of achieving healthy lifestyle overhauls in our patients to halt the progression of CVD. Our younger patients should be counseled to modify their lifestyles so that they don't gain weight, develop hypertension or hypercholesterolemia, or start smoking. For older patients, aged 40 to 50 years, who already have ≥2 major CV risk factors, the heightened lifetime risks of developing CVD (65% for men and 50% for wo- suggest the need to become even more aggr- with preventive therapies.[5]

lives."[6] Instead of being highlighted as an example of a behavioral change failure, what can we do to improve our rates of getting patients to make the necessary changes to lessen their risk? In this commentary, we provide some useful suggestions and strategies for counseling patients to change and maintain lifestyle behaviors that may favorably impact future CV morbidity and mortality.

ADVISING PATIENTS REGARDING LIFESTYLE CHANGE: ARE WE DOING ENOUGH?

According to a recent telephone survey of 153,000 adults in the United States, only 3% adhere to 4 healthy lifestyle characteristics, including not smoking, maintaining a normal body weight, eating adequate daily servings of fruits and vegetables, and exercising regularly.[7] Almost 10% of the respondents adhered to none of these practices.[8] Unfortunately,

**Preventive Cardiology, Winter 2008**

## Counseling Patients: Overcoming Inertia

For many patients, setting initial goals for selected risk factors may be unrealistic and discouraging, especially if contemporary guidelines and recommendations are used.

# Examples

- Counseling the patient who is 173 cm and 137 kg (BMI, 45.5 kg/m2) to reduce his weight to a "normal" range (i.e., 76 kg).
- Counseling the habitually sedentary patient to exercise for 30, 60, or even 90 minutes/day.

## Suggest Small Changes Rather Than Large Ones

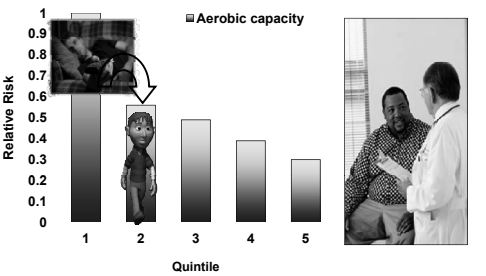
By achieving a small goal, the patient has initiated positive change. The rationale for this suggestion comes from self-efficacy theory.

Successful persuasion involves not only increasing a patient's faith in his or her capabilities, but also structuring interventions so that people are likely to experience success.

## Outline

- Treating "High Risk" Patient Subsets: Implications Regarding Outcomes
- Interventions & Outcome Modulators: Motivation, RTM
- The Future: Combining Pharmacotherapies + Lifestyle

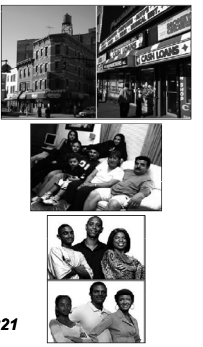

**Implications for Health Care Professionals: Moving Patients Out of the Least Fit, "High-Risk" Cohort (Bottom 20%)**




*Blair SN et al. JAMA 1996;276:205*
*Williams PT Med Sci Sports Exerc 2001;33:754*
*Franklin B et al. Mayo Clin Proc 2013;88:431*

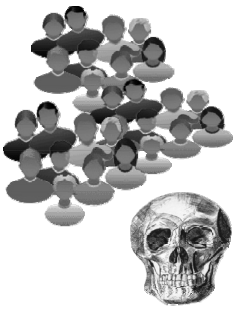
## The Case for Concentrating on the Less Fortunate

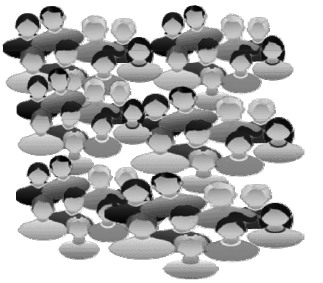
Since all the actionable determinants of health – personal behavior, social factors, health care, and the environment – disproportionately affect people with lower socioeconomic status, strategies to improve national health rankings must focus on this population.



***Schroeder SA. NEJM 2007;357:1221***

## Patient Subsets: Outliers = Increased Risk

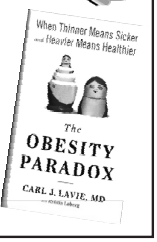




## Extreme BMIs = Increased Mortality

The study by Flegal et al* confirms that obese individuals with a BMI ≥ 35 are at increased risk of mortality, as are their underweight counterparts with a BMI < 18.5. The large BMI range between these extremes includes persons with differing adiposity, adipose tissue distribution, muscularity, nutritional status, and disease risk factors.

**Not all patients classified as being overweight or having grade I obesity (BMI of 30 ≤ 35), particularly those with chronic diseases, can be assumed to require weight loss treatment.**




* Flegal KM et al. JAMA 2013;309:71-82
† Heymsfield SB et al. JAMA 2013;309:87-88

## Sleep Duration Predicts Cardiovascular Outcomes*+

People reporting consistently sleeping short or long durations **(≤ 5 h and ≥ 9 h per night)** should be regarded as a high risk group for cardiovascular morbidity and mortality.

** Cappuccio FP et al. Eur Heart J 2011; Sabanayagam C et al. Sleep 2010*
*+ Hormonal imbalance, elevated risk factors, inflammation*

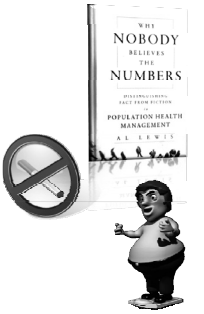
## Outline

- Treating "High Risk" Patient Subsets: Implications Regarding Outcomes
- Interventions & Outcome Modulators: Motivation, RTM
- The Future: Combining Pharmacotherapies + Lifestyle Modification

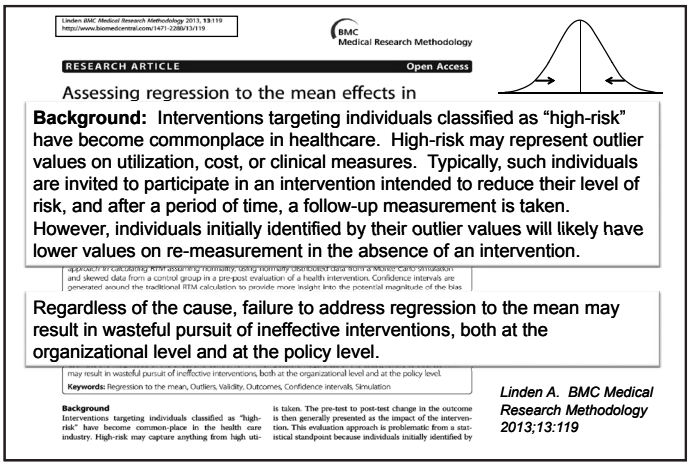


## Wellness Initiatives: Motivation Matters*

"The strongest predictor of whether someone will lose weight or stop smoking is how motivated they are. Since wellness interventions are usually voluntary, the most motivated individuals often sign up. That makes it impossible to credit the programs (per se) with success in smoking cessation or weight loss rather than the employees' motivation."




** Al Lewis, Disease Mgmt Purchasing Consortium Intl*



Linden BMC Medical Research Methodology 2013, 13:119
http://www.biomedcentral.com/1471-2288/13/119

BMC Medical Research Methodology

RESEARCH ARTICLE Open Access

Assessing regression to the mean effects in

**Background:** Interventions targeting individuals classified as "high-risk" have become commonplace in healthcare. High-risk may represent outlier values on utilization, cost, or clinical measures. Typically, such individuals are invited to participate in an intervention intended to reduce their level of risk, and after a period of time, a follow-up measurement is taken. However, individuals initially identified by their outlier values will likely have lower values on re-measurement in the absence of an intervention.

approach for calculating RTM assuming normality, using normally distributed data from a Monte Carlo simulation and skewed data from a control group in a pre-post evaluation of a health intervention. Confidence intervals are generated around the traditional RTM calculation to provide more insight into the potential magnitude of the bias

Regardless of the cause, failure to address regression to the mean may result in wasteful pursuit of ineffective interventions, both at the organizational level and at the policy level.

may result in wasteful pursuit of ineffective interventions, both at the organizational level and at the policy level.

**Keywords:** Regression to the mean, Outliers, Validity, Outcomes, Confidence intervals, Simulation

**Background**

Interventions targeting individuals classified as "high-risk" have become common-place in the health care industry. High-risk may capture anything from high uti- is taken. The pre-test to post-test change in the outcome is then generally presented as the impact of the intervention. This evaluation approach is problematic from a statistical standpoint because individuals initially identified by

*Linden A. BMC Medical Research Methodology 2013;13:119*

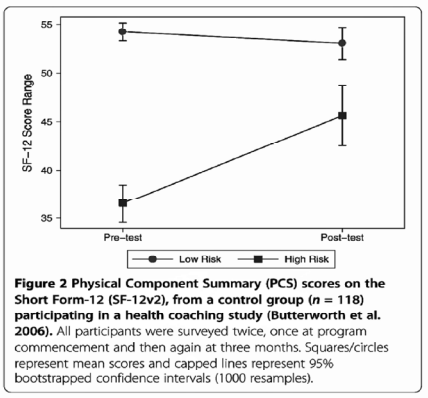


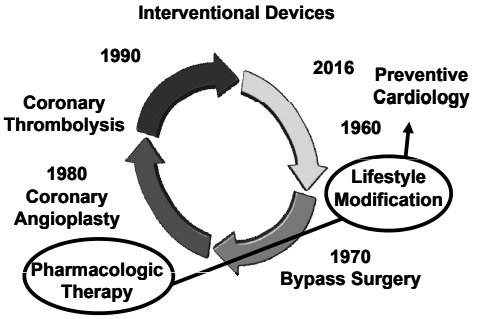

**Figure 2 Physical Component Summary (PCS) scores on the Short Form-12 (SF-12v2), from a control group ($n$ = 118) participating in a health coaching study (Butterworth et al. 2006).** All participants were surveyed twice, once at program commencement and then again at three months. Squares/circles represent mean scores and capped lines represent 95% bootstrapped confidence intervals (1000 resamples).

*Linden A. BMC Medical Research Methodology 2013;13:119*

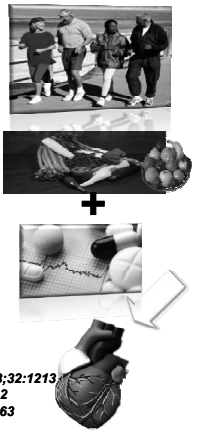
## Outline

- Treating "High Risk" Patient Subsets: Implications Regarding Outcomes
- Self Responsibility: Meeting Certain Risk Reduction Metrics ($ Penalties)
- The Future: Combining Pharmacotherapies + Lifestyle Modification

## Evolutionary Treatment of Heart Disease




## The effects of lifestyle change and drug therapy on cardiovascular risk reduction appear to be **independent and additive.**

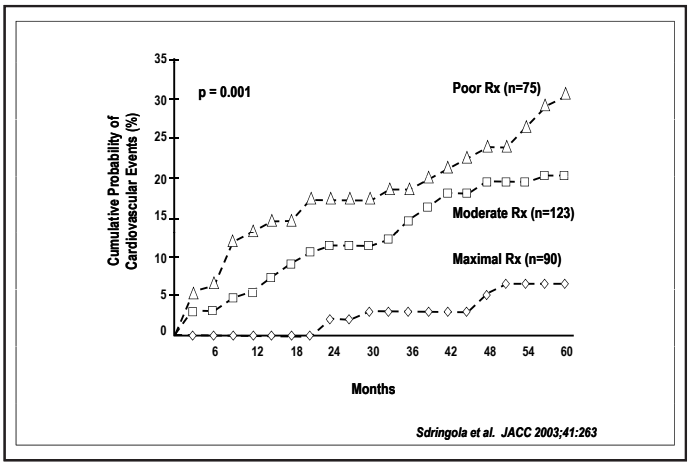


*Hunninghake DB et al. NEJM 1993;32:1213*
*Barnard RJ et al. AJC 1997;79:1112*
*Sdringola S et al. JACC 2003;41:263*

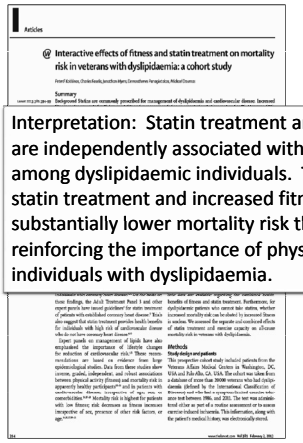
### Intensive Diet & Exercise in Patients Taking Cholesterol-Lowering Drugs*

Aggressive diet therapy (< 10% calories from fat [< 3% saturated]) combined with daily aerobic exercise results in **additional substantial reductions** in total cholesterol, LDL-cholesterol and triglycerides (19%, 20%, 29%, respectively), beyond those achieved with cholesterol-lowering drugs.

**Barnard RJ et al. AJC 1997;79:1112*




*Sdringola et al. JACC 2003;41:263*



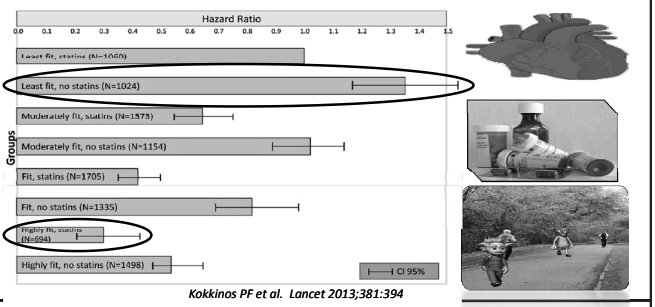
Articles

Interactive effects of fitness and statin treatment on mortality risk in veterans with dyslipidaemia: a cohort study

Interpretation: Statin treatment and increased fitness are independently associated with low mortality among dyslipidaemic individuals. The combination of statin treatment and increased fitness resulted in substantially lower mortality risk than either alone, reinforcing the importance of physical activity for individuals with dyslipidaemia.

*Kokkinos PF et al. Lancet 2013;381:394-99*

**Mortality Risk, Expressed as Adjusted Hazard Ratios ± 95 CI, for Combined Fitness and Statin Categories (n=10,004; 10 Year Follow-up)**




*Kokkinos PF et al. Lancet 2013;381:394*



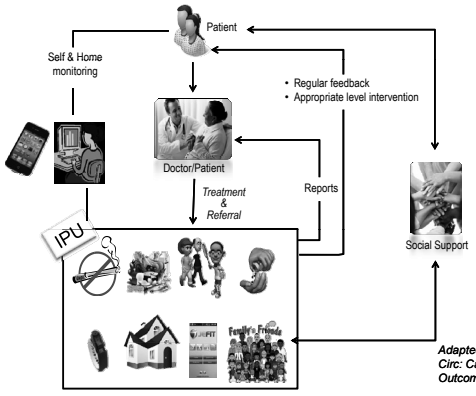
Beaumont

## Polypill: User Direction

Take medication each day in the prescribed dosage, followed or preceded by at least 30 minutes of moderate-to-vigorous physical activity, in combination with a low-fat, low-cholesterol diet, weight management, smoking cessation, and regular visits to your physician.

***Franklin B, Bonow R, et al AJC 2004;94:162***

## Future Healthcare Delivery




*Adapted from Magid DJ et al. Circ: Cardiovasc Quality and Outcomes 2013;32:1990*

SELF EVALUATION

## Moving from Reactive Sick Care to Proactive Healthcare

**1.** According to a recent *New England Journal of Medicine* article, the World Health Report ranked the U.S. Health care system _____ in the world, based on our outcomes (e.g., morbidity, longevity).

a. 8th
b. 15th
c. 20th
d. 37th

**2.** T/F - It appears that health care expenses are projected to soon account for $1 of every $5 spent in the U.S., representing 20% of the gross domestic product (GDP).

**3.** A landmark investigation using data from the longstanding Framingham Heart Disease Study, showed that adults who got to the age of 50 without any major cardiovascular risk factors had a lifetime risk of ever developing heart disease that approximated ___%.

a. 1
b. 7
c. 12
d. 20

**4.** Among persons at high cardiovascular risk, a Mediterranean diet supplemented with extra-virgin olive oil or nuts reduced the incidence of major cardiovascular events by ___%.

a. 20
b. 30
c. 40
d. 60

**5.** T/F - Regardless of the risk factor profile, low fit men and women have approximately 4 times the mortality as their age and gender matched high fit counterparts.

**6.** According to two landmark studies, continued smokers die, on average, about ____ years younger than lifelong non-smokers.

a. 2-3
b. 5-7
c. 10-12
d. none of the above

**7.** The single greatest contributor to premature death among U.S. citizens is _____.

a. health behaviors
b. limited access to medical care
c. environmental factors
d. genetics

**8.** T/F - A recent study confirmed a “U-shaped” curve between body mass index (BMI) and mortality, specifically that obese individuals with a BMI ≥ 30 are at increased risk of mortality, as are their underweight counterparts with a BMI < 20.

**Answer Key:** 1. D, 2. T, 3. B, 4. B, 5. F, 6. C, 7. A, 8. F

## David B. Mandell, JD, MBA

David B. Mandell, JD, MBA, of Ft. Lauderdale, Florida, is a practicing attorney and a principal of the financial consulting firm OJM Group. He specializes in risk management, asset protection and financial planning and has authored a number of books for doctors including, *For Doctors Only: A Guide to Working Less and Building More*. Mr. Mandell also created the Category 1 CME monograph, *Risk Management for the Practicing Physician*. His articles have appeared in over 100 publications, including over 30 medical specialty journals, and he has addressed many of the nation's leading medical conferences.

Mr. Mandell holds a bachelor's degree from Harvard University from which he graduated with honors, a law degree from the UCLA School of Law where he was awarded the American Jurisprudence Award for achievement in legal ethics, and earned his MBA from UCLA'S Anderson School of Management.

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# Reducing Risk and Protecting Assets

*David B. Mandell, JD, MBA*

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## OJM MATERIALS FREE TO AEI PARTICIPANTS


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## TODAY'S PRESENTATION

1. Background on physician stress
2. Risk management drill-down: texting
3. Asset protection background
4. Shielding cash flow & personal assets from potential risks

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## PHYSICIANS STRESSED ABOUT LIABILITY

1. 87 percent of respondents said they are moderately-to-severely stressed/burned out on an average day.*
2. Concern about liability and lawsuits are a motivating force behind the skyrocketing costs associated with "defensive medicine"**

*Of 2,000 physicians as reports by Bouchard, Stephanie, "Impact of Physician Stress Underestimated," *HealthCare Finance News*, December 2, 2011

**Peter Ubel, "Do Malpractice Fears Cause Physicians To Order Unnecessary Tests?" Forbes.com, October 22, 2013

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## TYPES OF LIABILITY FACING PHYSICIANS

- Medical malpractice
- Employer liability
  - Sexual harassment ("hostile work environment"); Wrongful termination (protected classes); Violation of fiduciary duty (qualified plans)
- Billing issues
  - Over-billing, improper billing, fraud, violation of anti-kickback rules, Stark rules, etc.
- HIPAA, premises liability, personal liability

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## RISK MANAGEMENT VS ASSET PROTECTION

- Risk management: improve behaviors to reduce risk and potential liability
  - Category I CME Monograph: ***Risk Management for the Practicing Physician***
- Asset protection: shield assets in case of liability – recognition that there is always risk
  - Other books, including ***For Doctors Only***

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## RISK MANAGEMENT DRILL DOWN: TEXTING

- 2012 Study: 73% of physicians texted other physicians about work*
- Risk: HIPAA violations for disclosure of protected health information (PHI). Specifically:
  - Text messages may reside on a mobile device indefinitely, and thus could be accessed if the device is ever lost, stolen or recycled.
  - Text messages are typically accessible with little, if any, authentication.
  - Text messages are often not monitored by the IT department

*Greene, Adam H. "HIPAA Compliance for Clinician Texting" Journal of AHIMA 83, no.4 (April 2012): 34-36.

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## RISK MANAGEMENT DRILL DOWN: TEXTING

Consider risk management for physician texting, including*:

- An administrative policy prohibiting the texting of ePHI or limiting the type of information that may be shared via text message
- Workforce training on the appropriate use of work-related texting
- Password protection and encryption for mobile devices that create, receive, or maintain text messages with ePHI
- An inventory of all mobile devices used for texting ePHI (whether provider-owned or personal devices)
- Proper sanitization of mobile devices that text ePHI upon retirement of the device
- A policy requiring annotation of the medical record with any ePHI that is received via text and is used to make a decision about a patient
- A policy setting forth a retention period or requiring immediate deletion of all texts that include ePHI
- Use of alternative technology, such as a **vendor-supplied secure messaging application**

OJMGROUP *Greene, Adam H. "HIPAA Compliance for Clinician Texting" Journal of AHIMA 83, no.4 (April 2012): 34-36.

## ASSET PROTECTION FUNDAMENTALS

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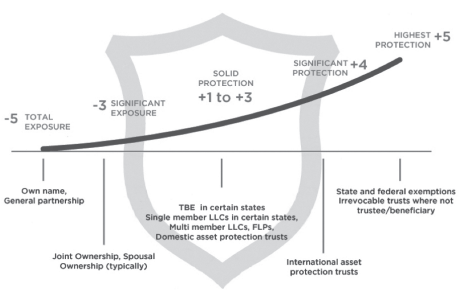
## ASSET PROTECTION "SLIDING SCALE"




*The scale presumes tools are created and utilized properly and when fraudulent transfer rules will not apply.

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## THE BEST ASSET PROTECTION NOT AP

- Why wealth protection MUST be tied to wealth creation: timing
- Like tax planning: economic substance
- Top (+5) tools are primarily not AP tools
- AP must be implemented in a multidisciplinary approach

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## MAXIMIZE PROTECTIVE BENEFIT PLANS

- **Shields #1 asset – cash flow**
- Qualified retirement plans (QRPs) (+5)
  - Pensions
  - Profit-Sharing Plans
  - 401(k)s
  - 403 (b)s
- Significant other benefits: present tax deductions, long term tax growth/hedge, retirement, etc.

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## QUALIFIED RETIREMENT PLANS (QRPS)

- If you are going to use QRPs, maximize your benefits:
  - Use proper formula to maximize what physicians can provide vs. employees
  - Be conscious of investment options and fees
  - Be careful of potential liability for under-performance of funds for employees as fiduciary

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## WHAT ABOUT IRAS?

- Federal bankruptcy protection (+5)
- Various widely among states
  - Ex. California
- Rolling into QRP?

### OTHER BENEFIT PLANS

- Non-qualified plans – depends on plan/state
- Significant other benefits: present tax deductions, long term tax growth/hedge, retirement, etc.

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## TITLING ASSETS: DOES IT PROTECT?

- Spousal
- Basics: Tenancy in common, joint tenancy
- Tenancy by the Entirety (TBE)
- Community Property

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## START WITH EXEMPT ASSETS (+5)

- (+5) Federal or state exempt asset
- No gifting, compliance, accounting fees or special taxes
- Protection cannot be matched by any other planning
- Federal bankruptcy exemptions for QRPs and IRAs
- States vary widely
  - Homestead
  - QRPs, IRAs
  - Life insurance and annuities

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## LLCS/FLPs (+2):
IDEAL FOR MOST ASSETS BEYOND EXEMPTIONS

- Inside Creditors
- Outside Creditors Isolates their lawsuit damage only to FLP/LLC property
  - Creditors can only get "charging order" against the FLP interest (+1 to +3) depending on use, compliance
  - Should tie into your estate plan
- "Building blocks" of asset protection
- Control and Access

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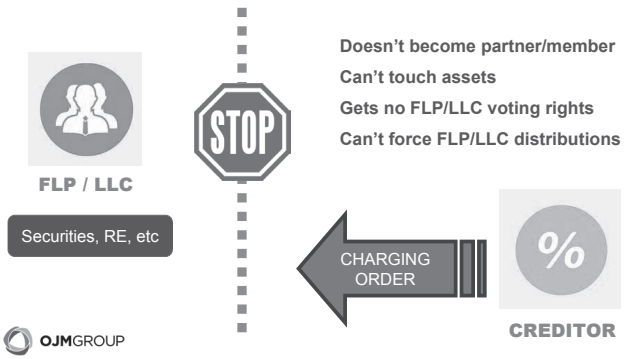
## WHAT A *CHARGING ORDER* MEANS

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## KEYS TO PROTECTION: FLPS/LLCS

- Proper partnership/operating agreement
- Compliance with annual formalities
- Non-asset protection purpose: estate planning/gifting
- Jurisdiction: use the best state, when you have options
- Many FLPs/LLCs are lacking in 1 of the 4 elements above: vulnerable
- Key: experienced attorney who has annual monitoring/gifting plan

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## USING TRUSTS TO SHIELD ASSETS

- Revocable trusts
  - "Family," "living," "loving trusts"
  - Valuable for probate avoidance, in event of incapacity
  - No asset protection while you are alive
- Irrevocable trusts
  - Many types, from ILITs to GRATs to CRTs, to DAPTs
  - Because they are irrevocable, strong asset protection
  - **DAPT is most innovative, newest**
    - **12 states**
    - **"Hybrid" version for other states**
    - **Different than FLPs LLCs**

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## PROTECTING THE HOME

- Homestead protection is best
- Tenancy by the entirety (TBE) in those states that protect TBE well
- Next best option:
  - Usually debt shield

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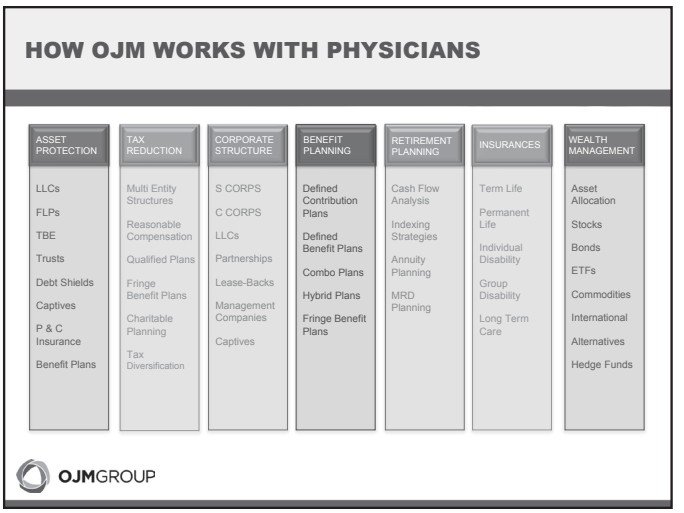


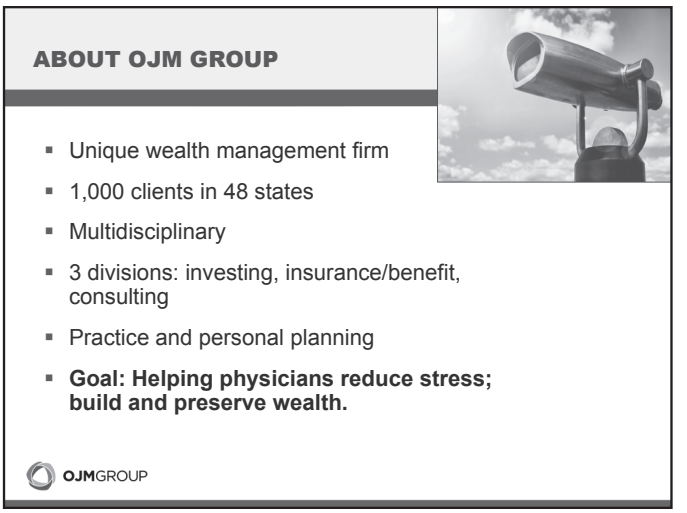


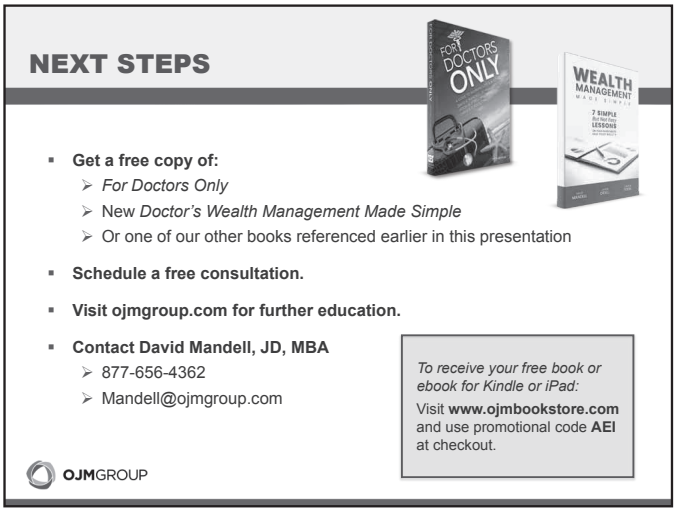


## SELF EVALUATION

### Reducing Risk and Protecting Assets

**1.** True/False - Concern about liability and lawsuits are a motivating force behind the growth of "defensive medicine."

**2.** According to the Healthcare Finance News survey referenced in the talk, the percentage of physicians surveyed who felt moderately-to-severely stressed was:

a. 17%
b. 37%
c. 47%
d. 87%

**3.** True/False - Medical malpractice is one of many potential liability sources for most doctors.

**4.** True/False - Asset protection is a discipline aimed at modifying behavior to reduce risk.

**5.** Risk management tactics to reduce potential HIPAA violations due to texting DO NOT include:

a. Use of limited liability companies
b. Use of secure messaging applications
c. Proper sanitization of mobile devices upon device retirement
d. Password protection for mobile devices

**6.** Which of the following asset protection tools generally get the top (+5) protective rating:

a. Family limited partnerships
b. Community property
c. Spousal ownership
d. State or federally exempt assets

**7.** Which are often called the "building blocks" of asset protection:

a. Non-qualified plans
b. Family limited partnerships and limited liability companies
c. Irrevocable trusts
d. Revocable trusts

**8.** True/False - Revocable trusts do not provide asset protection to you as the grantor while you are alive.

**Answer Key:** 1. T, 2. D, 3. T, 4. F, 5. A, 6. D, 7. B, 8. T

## C. Wayne Weart, PharmD, FASHP, BCPS

C. Wayne Weart, PharmD, of Charleston, South Carolina, is professor of the Department of Clinical Pharmacy and Outcome Sciences in the South Carolina College of Pharmacy, Medical University of South Carolina (MUSC), as well as professor of Family Medicine in the College of Medicine, MUSC. Prior to MUSC he instructed at West Virginia University.

Dr. Weart has authored more than 100 publications and he has presented hundreds of hours of lectures to numerous professional groups and societies, medical and house staffs at both West Virginia University and MUSC, and national pharmacy and medical seminars across the country. He has received numerous awards and honors in his field including: "Outstanding Teacher" awards at both West Virginia University and MUSC, "Hospital Pharmacist of the Year" in both South Carolina and West Virginia; and designation as a Fellow of the American Society of Health Systems Pharmacists. In 1991 Dr. Weart was among the first pharmacists to become a board certified Pharmacotherapy Specialist.

You may contact Dr. Weart at 843-792-3606, or by email at weartcw@musc.edu.

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## Pharmacotherapy Update - Parts 1 & 2

### Faculty Disclosure

- I do not have a vested interest in or affiliation with any corporate organization offering financial support or grant monies for this continuing education activity, or any affiliation with an organization whose philosophy could potentially bias my presentation.
- I do not speak for or consult with any pharmaceutical manufacturer.

### Zoster Vaccine

March 24, 2011 FDA approved – Zostavax for patients age 50-59 years

- Compared with placebo, **ZOSTAVAX significantly reduced the risk of developing zoster by 69.8% (95% CI [54.1 - 80.6%]) in 22,439 subjects 50 to 59 years of age.** Data from the Shingles Prevention Study demonstrated **64% (95% CI 56-71%) efficacy in patients age 60-69 years and 41% (95% CI 28 -52%) efficacy for patients age 70-79 years and. only 18% (95% CI -29 – 48%) efficacy in patients age 80 and above.**

### Zoster Vaccine

- **The Long-term persistence sub-study (LTPS) enrolled 6867 SPS vaccine recipients. Compared to SPS, estimated vaccine efficacy in LTPS decreased from 61.1% to 37.3% for the herpes zoster (HZ) burden of illness (BOI), from 66.5% to 35.4% for incidence of postherpetic neuralgia, and from 51.3% to 21.1% for incidence of HZ, and declined for all 3 outcome measures from 7 through 11 years post-vaccination.** Vaccine efficacy for the HZ BOI was significantly greater than zero through year 10 post-vaccination, whereas vaccine efficacy for incidence of HZ was significantly greater than zero only through year 8.
  - Clinical Infectious Diseases 2014; 60: 900-909

### Immunization Update – New Zoster sub-unit Vaccine – Shingrix By GSK

- **GSK reported the initial results of ZOE-50** a randomized, observer-blind, placebo-controlled, multi-center, multinational phase III efficacy study designed to assess HZ/su (herpes zoster/sub-unit vaccine**) in 16,160 patients age 50 and older.**
  - **viral protein (gE) combined with the adjuvant system** - AS01B (a liposome-based adjuvant system containing immunoenhancers) **(Not a live attenuated vaccine)**
  - **2-dose schedule at 0 and 2 months.**
  - **The vaccine efficacy** (defined as the reduction in disease incidence in the vaccinated group compared to the unvaccinated group) **in adults 50 years and older was 97.2%, compared to placebo.**
    - Study 110390. 2014. Available at: http://www.gsk-clinicalstudyregister.com/*
    - N Engl J Med 2015; 372:2087-2096 (May 28, 2015)

### HZ/su (herpes zoster/sub-unit vaccine) - Shingrix

- In **ZOE-70, 13,900 participants who could be evaluated (mean age, 75.6 years)** received either HZ/su (6950 participants) or placebo (6950 participants). During a **mean follow-up period of 3.7 years, herpes zoster occurred in 23 HZ/su recipients and in 223 placebo recipients (0.9 vs. 9.2 per 1000 person-years). Vaccine efficacy against herpes zoster was 89.8%** (95% confidence interval [CI], 84.2 to 93.7; P<0.001) and was **similar in participants 70 to 79 years of age (90.0%) and participants 80 years of age or older (89.1%).**
  - N Engl J Med 2016; 375:1019-1032
  - **GSK has filed with the FDA for approval on Oct 24, 2016**

### ACIP Meeting 10-25-2013

- **Fluzone High-Dose was 24.2% more effective in preventing influenza in 32,000 adults aged 65 years or older than regular Fluzone in a large-scale 2 year clinical trial conducted in the US and Canada**, vaccine maker Sanofi Pasteur told the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention today.
- **The rate of laboratory-confirmed influenza among participants receiving Fluzone High-Dose was 1.43% compared with 1.89% among patients immunized with Fluzone.** For the FDA to deem Fluzone High-Dose as superior, the vaccine needed to demonstrate a relative efficacy rate of at least 9.1%. It achieved a rate more than twice that — **RRR=24.2%, ARR = 0.46%, NNT 218**

## Adjuvant Flu Vaccine – Fluad

**by Seqirus Division of Australia's CSL (Commonwealth Serum Labs founded in 1915)**

- Nov 24, 2015 The U.S. Food and Drug Administration approved **Fluad, the first seasonal influenza vaccine containing an adjuvant.** Fluad, **a trivalent vaccine** produced from three influenza virus strains (two subtype A and one type B), is approved **for the prevention of seasonal influenza in people 65 years of age and older.**
  - **Developed and filed by Novartis which sold the influenza vaccine business to CSL in 2015**
  - Fluad was first approved for use in Italy in 1997 and is currently approved in 38 countries, including Canada and 15 European countries.

## Adjuvant Flu Vaccine – Fluad

- Fluad, which is manufactured using **an egg-based process, is formulated with the adjuvant MF59, an oil-in-water emulsion of squalene oil.** Squalene, a naturally occurring substance found in humans, animals and plants, is highly purified for the vaccine manufacturing process.
  - Adjuvants are incorporated into some vaccine formulations to enhance or direct the immune response of the vaccinated individual.

## Adjuvant Flu Vaccine – Fluad

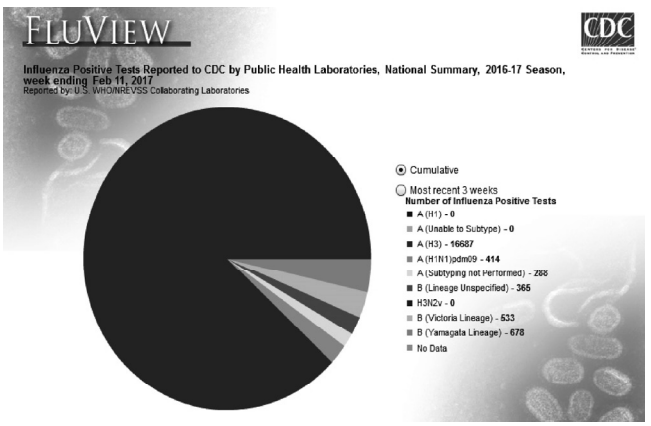
- **In individuals 65 years of age and older**. In that trial, **7,082 participants received either Fluad or Agriflu.** The study showed that **Fluad induced antibody levels that were comparable to the levels induced by Agriflu.**
- Safety was also evaluated in approximately 27,000 additional individuals 65 years of age and older. **No safety concerns were identified with Fluad**. The most common adverse events reported include injection site pain and tenderness, muscle aches, headache and fatigue.

## ACIP Meeting 6-22-2016

- **The committee has recommended against any use of the nasal vaccine (FluMist) for the upcoming season.**
- The ACIP weighed "data showing poor or relatively lower effectiveness" from three previous flu seasons. In late May, the body received **data showing that FluMist was just 3% effective in children aged 2 to 17 during the 2015-2016 flu season, compared with an estimated 63% effectiveness for flu shots**. ACIP said **"no protective benefit could be measured"** from the nasal vaccine.
- **The committee voted (13 yes, 1 no, 1 abstain for conflict of interest) to remove LAIV from the Vaccines for Children (VFC) program**. The IIV component of the program will not be changed.

## New Option for Flu Vaccine in Young Children for 2016-17

- GSK announced Nov 18, 2016 that the FDA had approved **FluLaval® Quadrivalent (Influenza Vaccine) to include use in children 6 months and older. (previously approved for age 3 and older)**
- This means that **both Fluzone and FluLaval can be used in children 6 months of age and older**



## Antiviral Resistance of Influenza Viruses

- **The WHO Collaborating Center for Surveillance, Epidemiology, and Control of Influenza at CDC tested 807 influenza virus specimens** (94 influenza A (H1N1)pdm09, 519 influenza A (H3N2), and 194 influenza B viruses) **collected in the United States from October 1, 2016, through February 4, 2017, for resistance to the influenza neuraminidase inhibitor antiviral medications oseltamivir, zanamivir, and peramivir,** drugs currently approved for use against seasonal influenza. **All 807 influenza viruses tested were found to be sensitive to all three antiviral medications**. An additional 114 influenza A (H3N2) viruses were tested for resistance to oseltamivir and zanamivir, and were found to be sensitive to both antiviral medications.
  – MMWR February 17, 2017 / 66(6);159–166

## 2016-2017 Influenza Vaccine Effectiveness

- **Interim estimates of vaccine effectiveness based on data collected from November 28, 2016, through February 4, 2017, indicate that overall the influenza vaccine has been 48% (95% confidence interval [CI] = 37%–57%) effective in preventing influenza-related medical visits across all age groups,** and specifically was **43% (CI = 29%–54%) and 73% (CI = 54%–84%) effective in preventing medical visits associated with influenza A (H3N2) and influenza B, respectively**.
- **Most influenza infections this season have been caused by influenza A (H3N2). This virus poses "special challenges," they said, because it undergoes more frequent and extensive genetic changes than either the H1N1 A or influenza B strains.** Because of this, it requires more frequent vaccine updates to "maintain activity against evolving circulating strains."
- This year's flu shot has been **most effective against H3N2 A viruses among children ages 6 months to 8 years (vaccine effectiveness 53%,** 95% CI 16%-74%) **and adults 50-64 years old (50%,** 95% CI 23%-67%).
  – MMWR February 17, 2017 / 66(6);159–166

## CDC who has received Flu Vaccine this year?

- Children 6 months thru 17 years of age: 37%
- People age 18 thru 64 years of age: 37%
- People age 65 and older: 57%
- Pregnant women: 47%
  – MMWR Feb 17, 2017

## Meningitis type B Vaccine – Trumenba

- **4-14-2016 FDA approved a revision to the dosage recommendations for Trumenbra to include a two-dose schedule (a dose administered at 0 and 6 months)** according to the regulations for accelerated approval **and a modification of the three-dose schedule from administration at 0, 2, and 6 months to administration at 0, 1-2, and 6 months.**

## ACIP Meeting 10-19-2016

- CDC Advisory Committee on Immunization Practices votes to recommend new dosing schedule for vaccination with Trumenba (meningococcal Group B vaccine)
  – **persons at increased risk for meningococcal disease, 3 doses of Trumenba** should be administered at 0, 1-2,6 months
  – **use during serogroup B outbreaks, 3 doses of Trumenba** should be administered at 0, 1-2, and 6 months
  – **minors not at increased risk for meningococcal disease, 2 doses of Trumenba to be given at 0,6 months**
    - **If the second dose is given at an interval of less than 6 months, a third dose should be given at least 6 months after the first dose**

## Meningitis type B Vaccine – Bexsero by Novartis (GSK)

- 1/23/2015 FDA granted accelerated approval of Bexsero® (Meningococcal Group B Vaccine [recombinant, adsorbed]) for **active immunization to prevent invasive meningococcal disease caused by serogroup B in adolescents and young adults from 10 years through 25 years of age.**
- Bexsero®, a multi 4-component Meningococcal B (MenB) vaccine (recombinant, adsorbed) suspension for injection 0.5 ml pre-filled syringe
- **Administer two doses (0.5 mL each) of BEXSERO IM in the deltoid at least 1 month apart.**

## ACIP Meeting Feb 26, 2015

- The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) voted to recommend either of the serogroup B meningococcal vaccinations to help protect individuals at increased risk. Specifically, **the ACIP voted to recommend serogroup B meningococcal vaccination for persons aged 10 years and older (CDC recommends at age 16-18) at increased risk for meningococcal disease, including:**
  - **Persons with persistent complement component deficiencies (`100,000 pts)**
  - **Persons with anatomic or functional asplenia (~90,000 pts)**
  - **Microbiologists routinely exposed to isolates of Neisseria meningitidis**
  - **Persons identified to be at increased risk because of a serogroup B meningococcal disease outbreak**

## ACIP Meeting 6-24-25, 2015

- **Serogroup B meningococcal vaccines series were approved by the committee as "category B" vaccination, defined as a vaccine for use on the basis of individual clinical decision-making, not for routine use among the recommended age group.**
- The recommendations stated that the serogroup B meningococcal vaccine series is for patients aged 16 to 23 years, although ACIP suggests patients aged 16 to 18 years as the preferred recipients of the vaccine.
- **Committee members also recommended that serogroup B meningococcal vaccine series be added to the immunization schedule table, as opposed to being added as a footnote.**
  - MMWR - October 23, 2015 / 64(41);1171-6

## Meningococcal ACWY Update 2017

- The need for a **quadrivalent meningococcal conjugate vaccine (MenACWY) booster at age 16 years.**
- **Meningococcal ACWY is now recommended for children with HIV.**
- **Adults with HIV infection who have not been previously vaccinated should receive a 2-dose primary MenACWY vaccination series, with doses administered at least 2 months apart, and be revaccinated every 5 years. Those who previously received 1 dose of MenACWY should receive a second dose at least 2 months after the first dose.**
- **MenB is not routinely recommended for adults with HIV infection, because meningococcal disease in this population is caused primarily by serogroups C, W, and Y.**
  - MMWR February 10, 2017 / 66(5);136–138

## HPV9 Vaccine – Gardasil-9 by Merck

- December 10, 2014 The FDA approved nine-valent HPV vaccine (V503) **Gardasil -9 that includes coverage for 6, 11, 16, and 18—just like HPV4—but also for five additional high cancer-risk strains: 31, 33, 45, 52, and 58.**
  - What might it offer vs. the current vaccines?
    - Additional 25% CIN 2 or cervical lesions
    - Additional 18% vaginal cancer cases
    - Additional 15% cervical cancer cases
    - Additional 4% of oropharyngeal cancer cases
    - The **FDA has stated that "Gardasil 9 has the potential to prevent approximately 90 percent of cervical, vulvar, vaginal and anal cancers."**

## ACIP Meeting Feb 26, 2015

- Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices **(ACIP) voted to include GARDASIL®9 (Human Papillomavirus 9-valent Vaccine, Recombinant) in the recommendations for use of HPV vaccines. GARDASIL 9 has been added to the routine recommendations for vaccination of 11- and 12- year-old females and males.**
  - The vaccination series can be started at age nine. **Vaccination is also recommended for females aged 13 to 26 and for males aged 13 to 21 who have not been vaccinated previously or have not completed the 3-dose series.**
  - **GARDASIL 9 has been added to the CDC's Vaccines for Children (VFC) program for both boys and girls.**

## ACIP Meeting June 2016

- **GlaxoSmithKline has decided to withdraw its 2vHPV vaccine from the U.S. market by November 2016**, and Merck will withdraw its HPV-4 vaccine by the end of 2016, **leaving only the HPV-9 vaccine available in the United States.**
- **ACIP discussed the data on a two dose series of HPV-9 in 9-14 girls which was as effective as the 3 dose series in girls 15-26 y/o as long as the second dose is administered 6-12 mo after the first dose.** If the second dose is given prior to 6 mo a 3 doses series is indicated. The **ACIP did not vote and no recommendations are being issued at this time for the 2 dose series.**

## ACIP Meeting 10-19-2016

- The **ACIP recommended that 11- to 12-year-olds receive 2 doses of human papillomavirus (HPV) vaccine at least 6 months apart rather than the previously recommended 3 doses** to protect against cancers caused by HPV infections. **Teens and young adults who start the series later, at ages 15 through 26 years, will continue to need 3 doses of HPV vaccine** to protect against cancer-causing HPV infection.
- October 7, 2016, the FDA approved adding a 2-dose schedule for 9-valent HPV vaccine (Gardasil 9) for adolescents aged 9 through 14 years

## ACIP Meeting 10-19-2016

- The **ACIP recommended that 11- to 12-year-olds receive 2 doses of human papillomavirus (HPV) vaccine at least 6 months apart rather than the previously recommended 3 doses** to protect against cancers caused by HPV infections. **Teens and young adults who start the series later, at ages 15 through 26 years, will continue to need 3 doses of HPV vaccine** to protect against cancer-causing HPV infection.
- October 7, 2016, the FDA approved adding a 2-dose schedule for 9-valent HPV vaccine (Gardasil 9) for adolescents aged 9 through 14 years

## Tdap in Pregnancy Update 2017

- The recommendation to vaccinate mothers, including adolescent mothers, as early as possible in the 27- to 36-week gestational window. **The words "as early as possible" were added because evidence shows that when the immunization is given closer to 27 weeks, "the baby is born with a higher concentration of maternal antibodies.**
- **The most severe complications for pertussis occur in the first 2 months of a child's life, yet infants cannot receive the pertussis vaccine before 2 months of age.**
  - MMWR February 10, 2017 / 66(5);136–138

## Hepatitis B Update 2017

- **New with this schedule is that one dose of the monovalent hepatitis B vaccine is recommended for all newborn children within 24 hours of birth.**
  - Previously, a birth dose was recommended, but that was interpreted to mean the first couple of weeks of life.
  - "There are about 25,000 babies a year born to mothers who are chronically infected with hepatitis B. We know that the **risk of transmission to a baby from a mother chronically infected can be as high as 90%. And we know, if babies are infected at birth, they have a significant risk of developing cirrhosis or cancer of the liver."**
  - MMWR February 10, 2017 / 66(5);136–138

## Hepatitis B Vaccine 2017

- The **second dose should be administered at age 1 or 2 months. Monovalent HepB vaccine should be used for doses administered before age 6 weeks.**
- Infants who did not receive a birth dose should receive 3 doses of a HepB-containing vaccine on a schedule of 0, 1 to 2 months, and 6 months, starting as soon as feasible
- Administer the second dose 1 to 2 months after the first dose (minimum interval of 4 weeks); **administer the third dose at least 8 weeks after the second dose AND at least 16 weeks after the first dose. The final (third or fourth) dose in the HepB vaccine series should be administered no earlier than age 24 weeks**
  - MMWR February 10, 2017 / 66(5);136–138

## Hepatitis B Vaccine 2017

- **Adults with chronic liver disease, including, but not limited to, hepatitis C virus infection, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, and an alanine aminotransferase (ALT) or aspartate aminotransferase (AST) level greater than twice the upper limit of normal should receive a HepB series.**
  - MMWR February 10, 2017 / 66(5);136–138

## Statin Use for the Primary Prevention of Cardiovascular Disease in Adults by USPSTF 11/2016

- **Adults aged 40 to 75 years with no history of CVD, 1 or more CVD risk factors, and a calculated 10-year CVD event risk of 10% or greater**
- The USPSTF recommends that **adults without a history of cardiovascular disease (CVD) (ie, symptomatic coronary artery disease or ischemic stroke) use a low- to moderate-dose statin for the prevention of CVD events and mortality when all of the following criteria are met: 1) they are aged 40 to 75 years; 2) they have 1 or more CVD risk factors (ie, dyslipidemia, diabetes, hypertension, or smoking); and 3) they have a calculated 10-year risk of a cardiovascular event of 10% or greater.**
- **Grade B Recommendation JAMA. 2016;316(19):1997-2007**

## LDL-C and Atherosclerotic CV Disease: Cause or Surrogate Marker?

- Low-density lipoproteins cause atherosclerotic cardiovascular disease. 1. Evidence from genetic, epidemiologic, and clinical studies. A consensus statement from the European Atherosclerosis Society Consensus Panel. 4/25/2017
- **Conclusion: "Consistent evidence from numerous and multiple different types of clinical and genetic studies unequivocally establishes that LDL causes ASCVD."**
- **LDL-C should no longer be considered a surrogate marker for ASCVD.**
  - **European Heart Journal (2017) 0, 1–14 doi:10.1093/eurheartj/ehx144**

## Low-density lipoprotein (LDL) as a causal factor for atherosclerotic cardiovascular disease: key implications

- **Cumulative LDL arterial burden is a central determinant for the initiation and progression of atherosclerotic cardiovascular disease.**
- **The lower the LDL cholesterol (LDL-C) level attained by agents that primarily target LDL receptors, the greater the clinical benefit accrued.**
- **Both proportional (relative) risk reduction and absolute risk reduction relate to the magnitude of LDL-C reduction.**
- **Lowering LDL-C in individuals at high cardiovascular risk earlier rather than later appears advisable, especially in those with familial hypercholesterolaemia.**
  - **European Heart Journal (2017) 0, 1–14 doi:10.1093/eurheartj/ehx144**

## AACE 2017 Guidelines

**Table 6**
**Atherosclerotic Cardiovascular Disease Risk Categories and LDL-C Treatment Goals**

| Risk category | Risk factors[a]/10-year risk[b] | Treatment goals | | |
|---|---|---|---|---|
| | | LDL-C (mg/dL) | Non-HDL-C (mg/dL) | Apo B (mg/dL) |
| Extreme risk | – Progressive ASCVD including unstable angina in patients after achieving an LDL-C <70 mg/dL<br>– Established clinical cardiovascular disease in patients with DM, CKD 3/4, or HeFH<br>– History of premature ASCVD (<55 male, <65 female) | <55 | <80 | <70 |
| Very high risk | – Established or recent hospitalization for ACS, coronary, carotid or peripheral vascular disease, 10-year risk >20%<br>– Diabetes or CKD 3/4 with 1 or more risk factor(s)<br>– HeFH | </0 | <100 | <80 |
| High risk | – ≥2 risk factors and 10-year risk 10-20%<br>– Diabetes or CKD 3/4 with no other risk factors | <100 | <130 | <90 |
| Moderate risk | ≤2 risk factors and 10-year risk <10% | <100 | <130 | <90 |
| Low risk | 0 risk factors | <130 | <160 | NR |

AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS AND
AMERICAN COLLEGE OF ENDOCRINOLOGY ENDOCRINE PRACTICE Vol 23 (Suppl 2) April 2017

## New FDA Approved Generics

- **Ezetimibe 10 mg (Generic Zetia) now FDA approved 12/12/2016 from: (Zetia 10 mg tabs $340.00/30)**
  - **Glenmark Pharm Ltd / Par - Endo (First to file 180 day exclusivity**
    - **$85.00 - $268.00/30**
  - Tea Pharm US -Sandoz
    - --Watson Labs Inc. -Mylan Pharm Inc.
- **Ezetimibe/Simvastatin 10/10, 10/20, 10/40 and 10/80 mg (Generic Vytorin) now FDA approved 4/26/2017 from:**
  - **Brand 10/40 mg $295.00 - $337.00/30; Generic 10/40 mg $86.00 - $289.00/30**
  - Dr. Reddys labs International
  - Impax Labs Inc.
  - Watson Labs Inc.

## IMPROVE-IT Trial

- The results of IMPROVE-IT (AHA 11/17/2014 Scientific Sessions). **The study included more than 18 000 patients from 39 countries who were stable following ACS (<10 days).** Patients were randomized to one of two treatment strategies**: simvastatin 40 mg alone or simvastatin 40 mg plus ezetimibe 10 mg.** They were followed for a minimum of 2.5 years or until the study investigators accrued 5250 clinical events.
- At baseline, the mean LDL-cholesterol level among the ACS patients was 95 mg/dL in both treatment arms. With **simvastatin 40 mg, LDL-cholesterol levels were reduced to 69.9 mg/dL at 1 year. The addition of ezetimibe 10 mg to simvastatin further lowered LDL-cholesterol levels, to 53.2 mg/dL at 1 year**. Over 7 years, there remained a significant difference between the two treatments in the achieved LDL-cholesterol levels.
  - N Engl J Med 2015; 372:2387-2397

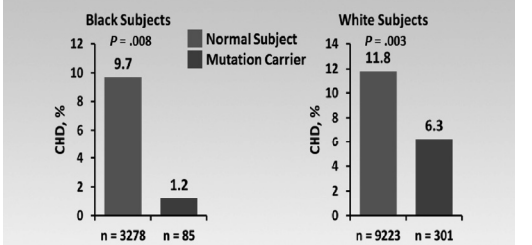
## IMPROVE-IT Trial

Primary End Point and Individual Components (7-Year Event Rates)

| Clinical Outcomes | Simvastatin, n=9077 (%) | Ezetimibe/Simvastatin, n=9067 (%) | *P* |
|---|---|---|---|
| Primary end point (Cardiovascular death, MI, unstable angina, coronary revascularization, or stroke) | 34.7 | 32.7 | 0.016 |
| All-cause death | 15.3 | 15.4 | 0.782 |
| MI | 14.8 | 13.1 | 0.002 |
| Stroke | 4.8 | 4.2 | 0.052 |
| Ischemic stroke | 4.1 | 3.4 | 0.008 |
| Unstable angina | 1.9 | 2.1 | 0.618 |
| Coronary revascularization | 23.4 | 21.8 | 0.107 |

**Primary combined endpoint at 7 years: RRR 6.4%; ARR 2.0%; NNT 50**
**MI at 7 years: ARR 1.7%; NNT 59**
**Ischemic stroke at 7 years: 0.7%; NNT 142**
**N Engl J Med 2015; 372:2387-2397**

## *PCSK9* Loss-of-Function Mutations Resulted in Low LDL-C Levels and Reduced CHD Rates[a]




- Wild-type PCSK9 degrades LDL receptors[b,c]
- Loss-of-function mutations increase hepatic *LDLR* expression, reducing LDL-C levels by 15%-40%[a,c]
- CHD was reduced 47%-88% in *PCSK9* loss-of-function mutation carriers compared with normal individuals[a]

a. Cohen JC, et al. *N Engl J Med*. 2006;354:1264-1272.
b. Peterson AS, et al. *J Lipid Res*. 2008;49:1595-1599.
c. Cohen J, et al. *Nat Genet*. 2005;37:161-165.

LIPID & METABOLIC

## Alirocumab-Praluent
### by Sanofi/Regeneron

- **July 24, 2015 the FDA approved alirocumab as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease, who require additional lowering of LDL-C.**
- The effect of alirocumab on cardiovascular morbidity and mortality has not been determined.

## Alirocumab-Praluent

- Supplied in single-dose pre-filled pens and single-dose pre-filled glass syringes. **Each pre-filled pen or pre-filled syringe is designed to deliver 1 mL of 75 mg/mL or 150 mg/mL solution**. (available in cartons containing 1 or 2, pre-filled pens and 1 or 2, pre-filled syringes).


- **Cost: $14,600.00/year**

## Alirocumab-Praluent

- **The recommended starting dose of alirocumab is 75 mg administered subcutaneously once every 2 weeks, since the majority of patients achieve sufficient LDL-C reduction with this dosage. If the LDL-C response is inadequate, the dosage may be increased to the maximum dosage of 150 mg administered every 2 weeks.**
- **Measure LDL-C levels within 4 to 8 weeks of initiating or titrating alirocumab to assess response and adjust the dose**, if needed. If a dose is missed, instruct the patient to administer the injection within 7 days from the missed dose and then resume the patient's original schedule.

## Alirocumab-Praluent

- **The efficacy of alirocumab was investigated in five double-blind placebo-controlled trials that enrolled 3499 patients; 36% were patients with heterozygous familial hypercholesterolemia (HeFH) and 54% were non-FH patients who had clinical atherosclerotic cardiovascular disease. All patients were receiving a maximally tolerated dose of a statin, with or without other lipid-modifying therapies.**
  - **Study 1:18% had HeFH. The average LDL-C at baseline was 122 mg/dL. At 24 weeks the lipid levels alirocumab 150 mg minus placebo were LDL-C -58%; TC -36%; Non HDL-C -50% and ApoB – 51%.**
  - **Studies 3 & 4: all had HeFH, average baseline LDL-C 141 mg/dl. At 24 weeks the lipid levels with alirocumab 75 up to 150 mg minus placebo were LDL-C -54%; TC -36%; Non HDL-C -49% and ApoB - 42%**

## Evolocumab – Repatha by Amgen

- **FDA approved 8-27-2015 a PCSK9 (proprotein convertase subtilisin kexin type 9) inhibitor antibody indicated as an adjunct to diet and: for the treatment of patients with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (CVD), who require additional lowering of low density lipoprotein cholesterol(LDL-C).**
- **Patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C when other LDL-C lowering therapies are not adequate (e.g., statins, ezetimibe, LDL apheresis).**

## Evolocumab – Repatha

- **The effect of evolocumab on cardiovascular morbidity and mortality has not been determined.**
- **Available as:**
  - **Injection: 140 mg/mL in a single –use prefilled syringe**
  - **Injection: 140 mg /mL in a single –use prefilled SureClick ® autoinjector**
  - **Cost: $542.31/140 mg dose WAC or about $14,100.00/year for the every other week dosage.**

Storage: Keep in the refrigerator. Prior to use, allow to warm to room temperature for at least 30 minutes. Alternatively, for patients and caregivers, the drug can be kept at room temperature (up to 25°C (77°F)) in the original carton. However, under these conditions , the medication must be used within 30 days.

## Evolocumab – Repatha

- Administer by **subcutaneous injection**
- Primary hyperlipidemia with established **clinical atherosclerotic CVD or HeFH:**
  - **140 mg every 2 weeks or 420 mg* once monthly in abdomen, thigh, or upper arm**
- **HoFH:**
  - **420 mg* once monthly**
  - ***To administer 420 mg, give 3 x 140 mg injections consecutively within 30 minutes Now we also have Pushtronex System**

## Evolocumab – Repatha

- **7/11/2016 The FDA approved Pushtronex system is an on-body infusor with a prefilled cartridge of evolocumab 420 mg for once a month administration.**
  - Amgen said that **the device adheres to the body and is hands-free.** While receiving the injection, patients are able to perform moderate physical activities. **injection takes ~ 9 minutes.** The system was collaboration with West Pharmaceutical Services.
- Price is expected to be similar to the 140 mg eve weeks or about $14,100.00/year

Repatha® (evolocumab) *Pushtronex*™ system (on-body infusor with prefilled cartridge)

## Evolocumab – Repatha

- Data **in patients with heterogygous familial hypercholesterolemia (HeFH):**
- A multicenter, double-blind, randomized, placebo-controlled, **12-week trial in 329 patients with heterozygous familial hypercholesterolemia (HeFH) on statins with or without other lipid-lowering therapies. Patients were randomized to receive subcutaneous injections of evolocumab 140 mg every two weeks, 420 mg once monthly, or placebo.**
  - The **average LDL-C at baseline was 156 mg/dL with 76% of the patients on high-intensity statin therapy**

## Evolocumab – Repatha

- Results after 12 weeks:
  - In these patients with HeFH on statins with or without other lipid lowering therapies, the **differences between evolocumab and placebo in mean percent change in LDL-C from baseline to Week 12 was -61% (95%CI: -67%, -55%; p < 0.0001) and -60% (95%CI: -68%, -52%; p < 0.0001) for the 140 mg every 2 weeks and 420 mg once monthly dosages, respectively. (Note no difference in the two regimens)**

## Evolocumab – Repatha

- **Data in patients with homozygous familial hypercholesterolemia (HoFH):**
- **A multicenter, double-blind, randomized, placebo-controlled, 12-week trial in 49 patients (not on lipid-apheresis therapy) with homozygous familial hypercholesterolemia (HoFH). In this trial, 33 patients received subcutaneous injections of 420 mg of evolocumab once monthly and 16 patients received placebo as an adjunct to other lipid-lowering therapies (e.g., statins, ezetimibe).**

## Evolocumab – Repatha

- Characteristics of the HoFH patients included:
  - The **mean age at baseline was 31 years, 49% were women, 90% White, 4% were Asian, and 6% other. The trial included 10 adolescents (ages 13 to 17 years), 7 of whom received evolocumab. The mean LDL-C at baseline was 349 mg/dL with all patients on statins (atorvastatin or rosuvastatin) and 92% on ezetimibe.** The diagnosis of HoFH was made by genetic confirmation or a clinical diagnosis based on a history of an untreated LDL-C concentration > 500 mg/dL together with either xanthoma before 10 years of age or evidence of HeFH in both parents.

## Evolocumab – Repatha

- Results after 12 weeks:
- In these patients with HoFH, the **difference between evolocumab and placebo in mean percent change in LDL-C from baseline to Week 12 was -31% (95%CI: -44%, -18%; p < 0.0001).**
- **Patients known to have two LDL-receptor negative alleles (little to no residual function) did not respond to evolocumab.**

## FOURIER

Further cardiovascular OUtcomes Research with PCSK9 Inhibition in subjects with Elevated Risk

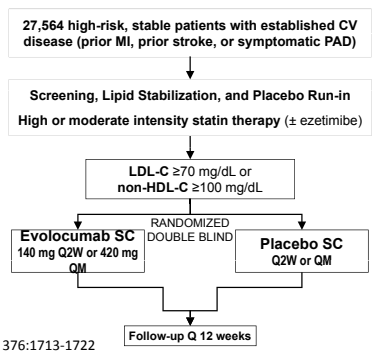
MS Sabatine, RP Giugliano, AC Keech, N Honarpour, SM Wasserman, PS Sever, and TR Pedersen, for the FOURIER Steering Committee & Investigators

*American College of Cardiology – 66th Annual Scientific Session*
*Late-Breaking Clinical Trial*
*March 17, 2017*

N Engl J Med 2017; 376:1713-1722

An Academic Research Organization of Brigham and Women's Hospital and Harvard Medical School

## Trial Design




N Engl J Med 2017; 376:1713-1722

Sabatine MS et al. *Am Heart J* 2016;173:94-101

## Endpoints

- **Efficacy**
  - **Primary: CV death, MI, stroke, hosp. for UA, or coronary revasc**
  - **Key secondary: CV death, MI or stroke**
- **Safety**
  - **AEs/SAEs**
  - **Events of interest incl. muscle-related, new-onset diabetes, neurocognitive**
  - **Development of anti-evolocumab Ab (binding and neutralizing)**
- **TIMI Clinical Events Committee (CEC)**
  - **Adjudicated all efficacy endpoints & new-onset diabetes**
  - **Members unaware of treatment assignment & lipid levels**

N Engl J Med 2017; 376:1713-1722

Sabatine MS et al. *Am Heart J* 2016;173:94-101

## Baseline Characteristics

fourier

| Characteristic | Value |
|---|---|
| **Age**, years, mean (SD) | **63 (9)** |
| **Male sex** (%) | **75** |
| **Type of cardiovascular disease** (%) | |
| Myocardial infarction | **81** |
| Stroke (non-hemorrhagic) | **19** |
| Symptomatic PAD | **13** |
| **Cardiovascular risk factor** (%) | |
| Hypertension | **80** |
| Diabetes mellitus | **37** |
| Current cigarette use | **28** |

Median time from most recent event ~3 yrs

N Engl J Med 2017; 376:1713-1722

Pooled data; no differences between treatment arms

## Lipid Lowering Therapy & Lipid Levels at Baseline

fourier

| Characteristic | Value |
|---|---|
| **Statin use** (%)* | |
| High-intensity | **69** |
| Moderate-intensity | **30** |
| **Ezetimibe use** (%) | **5** |
| **Median lipid measures** (IQR) – mg/dL | |
| LDL-C | **92 (80-109)** |
| Total cholesterol | **168 (151-189)** |
| HDL-C | **44 (37-53)** |
| Triglycerides | **133 (100-182)** |

*Per protocol, patients were to be on atorva ≥20 mg/d or equivalent.
1% were on low intensity or intensity data were missing.
Statin intensity defined per ACC/AHA 2013 Cholesterol Guidelines.

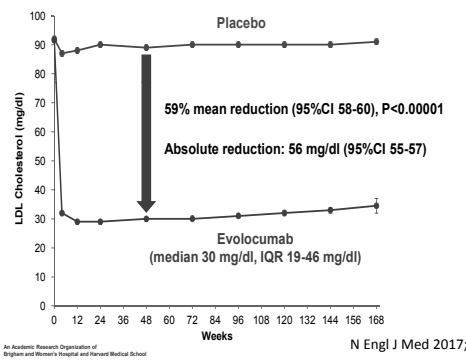
N Engl J Med 2017; 376:1713-1722

Pooled data; no differences between treatment arms

## LDL Cholesterol

TIMI

fourier




An Academic Research Organization of Brigham and Women's Hospital and Harvard Medical School

N Engl J Med 2017; 376:1713-1722

## Types of CV Outcomes

fourier

| Endpoint | Evolocumab (N=13,784) | Placebo (N=13,780) | HR (95% CI) |
|---|---|---|---|
| | *3-yr Kaplan-Meier rate* | | |
| **CVD, MI, stroke, UA, or revasc** | **12.6** | **14.6** | **0.85 (0.79-0.92) NNT 50** |
| **CV death, MI, or stroke** | **7.9** | **9.9** | **0.80 (0.73-0.88) NNT 50** |
| **Cardiovascular death** | **2.5** | **2.4** | **1.05 (0.88-1.25)** |
| **MI** | **4.4** | **6.3** | **0.73 (0.65-0.82) NNT 53** |
| **Stroke** | **2.2** | **2.6** | **0.79 (0.66-0.95) NNT 250** |
| **Hosp for unstable angina** | **2.2** | **2.3** | **0.99 (0.82-1.18)** |
| **Coronary revasc** | **7.0** | **9.2** | **0.78 (0.71-0.86) NNT 46** |
| Urgent | 3.7 | 5.4 | 0.73 (0.64-0.83) |
| Elective | 3.9 | 4.6 | 0.83 (0.73-0.95) |
| **Death from any cause** | **4.8** | **4.3** | **1.04 (0.91-1.19)** |

N Engl J Med 2017; 376:1713-1722

## Safety

fourier

| | Evolocumab (N=13,769) | Placebo (N=13,756) |
|---|---|---|
| **Adverse events** (%) | | |
| Any | **77.4** | **77.4** |
| Serious | **24.8** | **24.7** |
| Allergic reaction | **3.1** | **2.9** |
| Injection-site reaction | **2.1** | **1.6** |
| Treatment-related and led to d/c of study drug | **1.6** | **1.5** |
| Muscle-related | **5.0** | **4.8** |
| Cataract | **1.7** | **1.8** |
| Diabetes (new-onset) | **8.1** | **7.7** |
| Neurocognitive | **1.6** | **1.5** |
| **Laboratory results** (%) | | |
| Binding Ab | **0.3** | **n/a** |
| Neutralizing Ab | ***none*** | **n/a** |

New-onset diabetes assessed in patients without diabetes at baseline; adjudicated by CEC

N Engl J Med 2017; 376:1713-1722

## Summary for Evolocumab

fourier

- **↓ LDL-C by 59%**
  - Consistent throughout duration of trial
  - **Median achieved LDL-C of 30 mg/dl** (IQR 19-46 mg/dl)
- ↓ CV outcomes in patients already on statin therapy
  - 15% ↓ broad primary endpoint; 20% ↓ CV death, MI, or stroke
  - **Consistent benefit, incl. in those on high-intensity statin, low LDL-C**
  - 25% reduction in CV death, MI, or stroke after 1st year
  - Long-term benefits consistent w/ statins per mmol/L ↓ LDL-C
- Safe and well-tolerated
  - Similar rates of AEs, including DM & neurocog events w/ Evolocumab & placebo
  - **Rates of Evolocumab discontinuation low and no greater than placebo**
  - **No neutralizing antibodies developed**

N Engl J Med 2017; 376:1713-1722

## New Performance-Based Guaranteed Pricing?

- **In March, when cardiovascular outcomes (FOURIER Trial) results were presented for evolocumab (Repatha)** at the 66th Scientific Sessions of the American College of Cardiology (ACC), manufacturer **Amgen announced a first-of-its-kind offer: the company would pay a refund for all eligible patients who had a heart attack or stroke while taking the cholesterol-fighting injection.**
- This week (5-8-2017), Amgen announced that that health services company **Harvard Pilgrim has taken the deal.** The company, which covers 2.7 million people centered in New England, has signed **an outcomes-based contract** that some call groundbreaking and others say don't address the high price of the drug, which lists for more than $14,000 a year but reduces low-density lipoprotein (LDL) cholesterol by 60%.
- At ACC, the results of **the FOURIER trial showed that evolocumab reduced the combined risk of heart attack, stroke, and cardiovascular death 15% to 20%, and 25% beyond the first year. No early death reduction in overall deaths were seen.**
  - AJMC.com In Focus Blog 5-7-2017

## Cognition Sub-Study from FOURIER Trial

- **EBBINGHAUS (Evaluating PCSK9 Binding antiBody Influence oN coGnitive HeAlth in high cardiovascUlar risk Subjects) is a double-blind, placebo-controlled randomized non-inferiority trial involving approximately 1,900 patients enrolled in the FOURIER outcomes study**. Executive function (Spatial Working Memory strategy index primary endpoint) and secondary endpoints of working memory, memory function, and psychomotor speed were assessed using a tablet-based tool (CANTAB) at baseline and select time points.
- **The EBBINGHAUS cognitive function trial conducted in FOURIER patients also achieved its primary endpoint, demonstrating that Repatha was non-inferior to placebo for the effect on cognitive function.**
  - **Giugliano RP, Mach F, Zavitz K, et al. Primary results of EBBINGHAUS, a cognitive study of patients enrolled in the FOURIER trial. American College of Cardiology 2017 Scientific Sessions; March 18, 2017; Washington, DC. Abstract 17-LB-16161-AC.**

## EBBINGHAUS Cognition Sub-Study

**In patients with known cardiovascular disease on background statin followed for 20 months**

- **1. No differences btw evolocumab vs placebo**
  - A. A battery of cognitive tests
  - B. Patient-reported everyday cognition
  - C. Adverse cognitive events reported by MD
- **2. No evidence of differences in cognitive tests by achieved nadir LDL-C, even <25 mg/dL**
  - Giugliano RP, Mach F, Zavitz K, et al. Primary results of EBBINGHAUS, a cognitive study of patients enrolled in the FOURIER trial. American College of Cardiology 2017 Scientific Sessions; March 18, 2017; Washington, DC. Abstract 17-LB-16161-AC.

## Evolocumab – Repatha vs. Alirocumab-Praluent?

- **In March 2016 a US District Judge ruled that Sanofi and Regeneron violated the patent for Amgen's evolocumab (Repatha) which was appealed by Sanofi and Regeneron but on January 9, 2017 the Federal Judge issued an injunction that they must stop selling Praluent within 30 days but a second appeal to the US Court of Appeals is anticipated. The outcome of that appeal is likely to be known by the end of 2017 but we are already seeing a move towards increased market share for evolocumab (Repatha).**
- An alternative solution would be for the companies to agree on a settlement where Amgen would receive royalties from Sanofi and Regereron with both drugs remaining available.

## COPD Treatment: GOLD 2017 Guidelines

- Long-acting bronchodilators. **Almost all patients with COPD who experience more than occasional dyspnea should be prescribed long acting bronchodilator therapy.** This **could be a long-acting beta agonist (LABA), a long acting muscarinic antagonist (LAMA), or both. Patients with persistent COPD symptoms while taking one long-acting bronchodilator should be prescribed two (or a combination agent containing two long acting bronchodilators).**
- **Inhaled corticosteroids are not recommended as monotherapy in COPD.** Combination agents containing inhaled corticosteroids along with long-acting beta agonists are considered appropriate step-up therapy for patients experiencing COPD exacerbations while taking long-acting bronchodilators.
- **Oral PDE4 inhibitors are considered an add-on therapy only for patients with COPD with chronic bronchitis and severe airflow restriction who experience COPD exacerbations despite use of a combination bronchodilator with inhaled corticosteroid.**

## COPD Treatment: GOLD 2017 Guidelines

- Although specific drugs aren't advised, the GOLD path through Grade B and C (i.e., **most of the 11 million people living with COPD in the U.S.) advises dual therapy with a LABA and LAMA.**
- **Once-daily combination inhalers for COPD will likely result in better adherence**, which could result in **improved health outcomes compared to twice-daily regimens requiring multiple devices.**
- **The best inhaler for COPD is the one a patient can afford, understands, agrees with and will use regularly.**

Global Strategy for Diagnosis, Management and Prevention of COPD

## Therapeutic Options: Combination Therapy

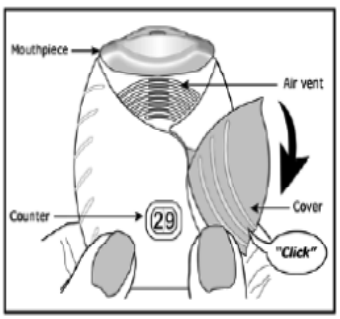
- An inhaled corticosteroid combined with a long-acting beta$_2$-agonist is more effective than the individual components in improving lung function and health status and reducing exacerbations in moderate to very severe COPD.
- Combination therapy is associated with an increased risk of pneumonia.
- Addition of a long-acting beta$_2$-agonist/inhaled glucorticosteroid combination to an anticholinergic (tiotropium) appears to provide additional benefits.



## Fluticasone furoate /Vilanterol inhalation powder –Breo Ellipta by GSK/Theravance

- Maintenance treatment of COPD: 1 inhalation of **Breo Ellipta 100 mcg/25 mcg (fluticasone furoate /vilanterol inhalation powder) once daily.**
- **Cost ~$310.00 Goodrx.com**
- **FDA Box Warning as with all other LABA containing medications Asthma Related Deaths but NOT indicated for patients with asthma**

## Fluticasone furoate /Vilanterol inhalation powder –Breo Ellipta




Be careful, every time you move the cover you move to the next dose!

## Fluticasone furoate /Vilanterol inhalation powder –Breo Ellipta

- **March 19, 2015 the FDA Advisory Committees (Pulmonary, Allergy, Drug safety) voted 16 to 4 to recommend Breo Ellipta for adults 18 y/o and older with asthma but also voted 18-2 against approval for children ages 1-17 y/o.**
- The panel also voted 17-3 that the data supported safety in adults but only one panel member voted that safety was supported in children.

## ICS/LABA Combination in Children?

- A multicenter trial **(VESTRI) randomly assigned 6208 children 4 to 11 years of age who had an asthma exacerbation in the previous year to a combination inhaler with fluticasone propionate (100 mcg or 250 mcg/inhalation) plus salmeterol (Advair) or to monotherapy with fluticasone propionate (100 mcg or 250 mcg/inhalation), one inhalation twice daily for 26 weeks.**
- **The number of patients who had a severe asthma exacerbation was 25% lower among children who continued taking fluticasone–salmeterol than among those who switched to fluticasone alone.**
- **Serious adverse events (hospitalization due to asthma exacerbation) occurred in 27 of 3107 patients in the fluticasone-salmeterol group and in 23 of the 3101 patients in the fluticasone group, hazard ratio 1.28 (95% CI 0.73-2.27). No deaths or endotracheal intubations were reported**. This hazard ratio suggests that the risk of serious asthma-related events was similar between the two groups.
  - N Engl J Med. 2016 Sep;375(9):840-9

## ICS/LABA Combination in Adults/Adolescents

- **AUSTRI a multicenter, noninferiority trial, 11,679 adolescents (>/=12) and adults with persistent asthma were randomly assigned to take either inhaled fluticasone or the combination of inhaled fluticasone-salmeterol (Advair) for 26 weeks.** Combination therapy was administered using a single inhaler that contained both fluticasone and salmeterol.
- The **risk of a severe asthma exacerbation was 21% lower in the fluticasone-salmeterol group than in the fluticasone-only group** (hazard ratio, 0.79; 95% CI, 0.70 to 0.89),
- **The hazard ratio for a serious asthma-related adverse event in the fluticasone-salmeterol group compared with fluticasone alone was 1.03 (95% CI 0.64-1.66), suggesting no increased risk related to the addition of the LABA.** Furthermore, **no deaths occurred in either group**, and no difference was noted in the rate of asthma-related hospitalizations.
  - N Engl J Med. 2016;374(19):1822.

## ICS/LABA Combination in Adults/Adolescents

- **The combination of budesonide (80 mcg or 160 mcg) plus formoterol (Symbicort) was compared with budesonide (80 mcg or 160 mcg) in a multicenter trial of 11,693 patients aged 12 and older** with one to four asthma exacerbations in the previous year; 2 inhalations were used twice daily for 26 weeks.
- The **risk of an asthma exacerbation was 16 percent lower in the budesonide-formoterol group.**
- A **serious asthma-related event occurred in 43 of 5846 patients in the combination arm and in 40 of 5847 in the budesonide arm, hazard ratio 1.07 (95% CI 0.70-1.65),** suggesting a similar risk between the groups.
  – N Engl J Med. 2016 Sep;375(9):850-60.

## Umeclidinium and Vilanterol – Anoro Ellipta Inhaler by GSK/Theravance

**Contains two blisters: umeclidinium 62.5 mcg per blister and the other contains vilanterol 25 mcg per blister.**

**Maintenance treatment of COPD: 1 inhalation once daily**

**Cost: ~$330.00/ 30 doses Goodrx.com**

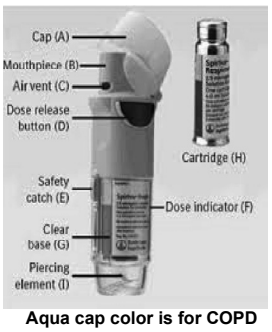

- **FDA Box Warning as with all other LABA containing medications Asthma Related Deaths but NOT indicated for patients with asthma**

## Umeclidinium – Incruse Ellipta Inhaler by GSK/Theravance

**Contains umeclidinium 62.5 mcg/ dose is an anticholinergic indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema**.

**Cost ~ $250.00 Goodrx.com**


## Tiotropium – Spiriva Respimat 2.5 mcg/inhalation for COPD by BI




**Aqua cap color is for COPD**

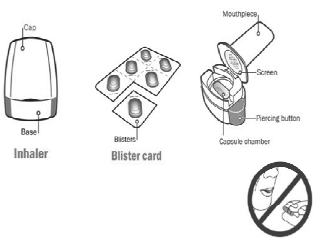
- FDA approved 9-25-2014; indicated as a maintenance bronchodilator treatment to relieve symptoms of patients with chronic obstructive pulmonary disease (COPD).
- The delivered **dose is 2.5 microgram tiotropium per puff (2 puffs/dose or 5 mcg)** and is equivalent to 3.124 microgram tiotropium bromide monohydrate
- **NOTE there are now two different inhalers!**
- **Cost ~ $350.00 Goodrx.com (both)**

## Tiotropium – Spiriva Respimat 1.25 mcg/inhalation for Asthma by BI

- **September 16, 2015 the FDA approved Spiriva Respimat for the long-term, once-daily, prescription maintenance treatment of asthma in people ages 12 and older. It is not a treatment for sudden asthma symptoms.**
- **Blue cap color is for patients with asthma!**
- Tiotropium **1.25 µg/puff (2 puff/dose or 2.5 mcg) is a long-term, once-daily,** prescription maintenance treatment of asthma for people 12 years and older.
- **Feb 2017 FDA approved down to age 6 years**

## Glycopyrrolate – Seebri Neohaler by Novartis

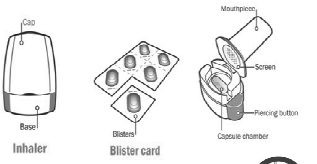
- **Oct 29, 2015 The U.S. Food and Drug Administration (FDA) approved Seebri Neohaler (glycopyrrolate) inhalation powder, a long-acting muscarinic antagonist (LAMA) indicated for the long-term maintenance treatment of airflow obstruction in patients 18 and older with chronic obstructive pulmonary disease (COPD).**
- **Dosed twice a day by inhalation (15.6 mcg /capsule for inhalation)**
- **Cost: $330.00/60 capsules GoodRx.com**




Store SEEBRI capsules in the blister, and only remove IMMEDIATELY BEFORE USE with the NEOHALER device. Each capsule contains approximately 25 mg of lactose monohydrate (which contains trace levels of milk protein).

## Combination of Glycopyrrolate and Indacaterol – Utibron Neohaler by Novartis

- **Oct 29, 2015 the FDA approved the combo of glycopyrrolate and indacaterol (a BID LABA/LAMA) for the maintenance treatment of patients with COPD.**
  - Capsules contain 27.5 mcg of indacaterol and 15.6 mcg glycopyrrolate inhalation powder for use with the NEOHALER device
  - Administered at the same time of the day, **(1 capsule in the morning and 1 capsule in the evening), every day.**
  - **Cost: $330.00/60 capsules GoodRx.com**




Store SEEBRI capsules in the blister, and only remove IMMEDIATELY BEFORE USE with the NEOHALER device. Each capsule contains approximately 25 mg of lactose monohydrate (which contains trace levels of milk protein).

## Combination of Glycopyrrolate and Formoterol – Bevespi Aerosphere by A/Z

- April 25,2016 the FDA approved **Bevespi a new LABA/LAMA co-suspension combination pressurized metered dose inhaler (pMDI) for twice a day maintenance therapy in patients with COPD**
- **Dose 2 inhalations twice a day 120 inhalations per pMDI**
- **Cost: $362.00/ canister GoodRx.com 1-25-17**
  - Prime 4 times prior to initial use, 2 times if not used for a week or more and after weekly rinsing of inhaler (NOT the canister!)

## Combination of Glycopyrrolate and Formoterol – Bevespi Aerosphere


- Shake well before each use
- Dose counter on top of canister (declines in 10's)
- Remove canister weekly and run inhaler device under warm water for 30 sec from both ends weekly to clean inhaler and let dry over night

## Tiotropium and Olodaterol - Stiolto Respimat

Stilto Respimat Inhalation Spray: 60 metered actuations **Cost: ~ $325.00**

- 5/21/2015 the FDA approved Boehringer Ingelheims **Fixed-Dose Combination Tiotropium Plus Olodaterol – Stiolto for Patients with COPD. (LAMA + LABA)**
  - The NDA submission for tiotropium + olodaterol FDC is based on results from three global Phase III trials in 7,000 pts – the 52-week replicate TONADO® 1&2 studies and the 6-week cross-over VIVACITO® dose finding study.

## Coming Soon: ICS/LABA/LAMA Combinations

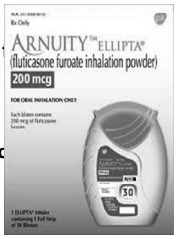
- **GSK announced 11/21/16 the filing with the FDA of a once-daily, closed triple combination therapy fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI 100/62.5/25 mcg) for patients with chronic obstructive pulmonary disease (COPD).**
- PT010 is a triple-drug combination of the long-acting muscarinic antagonist (LAMA) glycopyrronium, the long acting β2-agonist (LABA) formoterol fumarate and budesonide, an inhaled corticosteroid (ICS) by Pearl (both A/Z and Novartis are working on this combo)

## LAMA added to ICS/LABA in Patients with COPD **Chest. 2012;141(1):81**

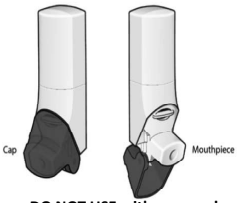
- **1,857 patients were given ICS + LABA + Tio, and 996 were given ICS + LABA. Mean follow-up was 4.65 years**. The adjusted **HR for all-cause mortality for ICS + LABA + Tio vs ICS + LABA was 0.65** (95% CI, 0.57-0.75; P<.001). Adjusted **HRs for hospital admissions and oral corticosteroid bursts were 0.85** (95% CI, 0.73-0.99; P = .04) **and 0.71** (95% CI, 0.63-0.80; P<.001), respectively.
- CONCLUSIONS The study suggests that the addition of tiotropium to ICSs and LABA therapy may confer benefits in reducing all-cause mortality, hospital admissions, and oral corticosteroid bursts in patients with COPD.

## Arnuity Ellipta (fluticasone furoate inhalation powder) by GSK/Theravance

- **FDA approved August 20, 2014 ARNUITY ELLIPTA is a corticosteroid indicated for: once-daily maintenance treatment of asthma as prophylactic therapy in patients aged 12 years and older. Not indicated for relief of acute bronchospasm.**
  - **In a 343 patient placebo controlled trial 100 mcg fluticasone furoate QD was similar to 250 mcg of propionate BID**
  - **Available in 100 and 200 mcg/inhalation Ellipta 30 dose dry powder inhaler**
  - **Cost ~ $150.00 per 100 mcg and ~$200.00/200 mc Goodrx.com**




## Albuterol sulfate inhalation powder – ProAir Respiclick by Teva




- **DO NOT USE with a spacer!**
- **200 actuations per device with a dose counter**
- **No priming required!**
- **Cost: ~ $55.00**
- **Do Not wash or put any part of your inhaler in water**

- FDA approved 4-1-2015 for **treatment (1-2 inhalations up to every 4-6 hours) or prevention of bronchospasm in patients 12 years of age and older with reversible obstructive airway disease and prevention of exercise-induced bronchospasm (15-30 min before exercise).**
  - **April 29, 2016 now FDA approved for children 4-11 years of age.**

## PROAIR RESPICLICK (albuterol sulfate) inhalation powder

**Step 2. Hold the inhaler upright as you open the cap fully.** See Figure F.

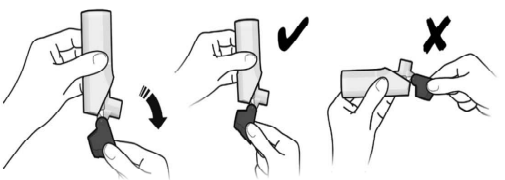


Figure F

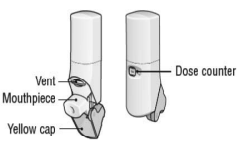
- Open the cap all the way back until you hear a "click".
- Your PROAIR RESPICLICK inhaler is now ready to use.
- Do not open the cap unless you are taking a dose.

## Fluticasone propionate /Salmeterol inhalation powder AirDuo RespiClick by Teva

- **FDA approved 1-27-2017 for the treatment of asthma in patients aged 12 years and older (one inhalation twice a day).**
- **Inhalation Powder containing fluticasone propionate 55 mcg, 113 mcg, or 232 mcg and salmeterol (14 mcg) per actuation.**
- **Class label "Asthma Related Death" as with all LABA's**
- **AirDuo RespiClick, is not directly substitutable for Advair and is only approved for asthma, while Advair is also widely used for chronic obstructive pulmonary disease (COPD).**

## Fluticasone propionate /Salmeterol inhalation powder AirDuo RespiClick

- **Fluticasone propionate/salmeterol xinafoate MDPI 118/13.2 mcg had similar clinical efficacy with lower systemic exposure when compared to the 50 mcg of salmeterol in fluticasone propionate/salmeterol 100/50 mcg dry powder inhaler**
- **AirDuo RespiClick has a yellow cap**
- **Instruct patients to not open their inhaler unless they are taking a dose. Repeated opening and closing the cover without taking medication will waste medication and may damage the inhaler.**
- Advise patients to **keep their inhaler dry** and clean at all times. **Never wash in wat**




## Fluticasone propionate /Salmeterol inhalation powder AirDuo RespiClick by Teva

- **Teva has announced that they will also launch a generic version of Air Duo RespiClick at the same time with an anticipated 70-80% lower price to gain formulary status and try to beat the generic Advairs from 2 or 3 manufacturers including Mylan and Hikma and Vectura.**

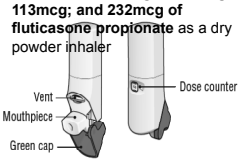
## Generic Advair (fluticasone/salmeterol)

- The U.S. Food and Drug Administration is due to decide whether to approve **the first of these, from Mylan, by March 28, 2017 but Mylan received a Complete Response Letter. A rival version from Hikma and Vectura is close behind, with an approval date of May 10.**
- According to the FDA: **"A complete response letter provides a more consistent and neutral mechanism to convey that our initial review of an application is complete and we cannot approve the application in its present form."**

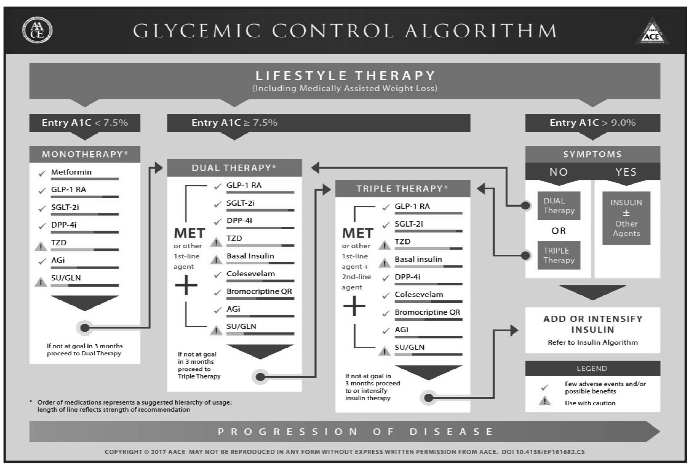
## Fluticasone propionate - ArmonAir RespiClick by Teva

FDA approved for **maintenance treatment of asthma as prophylactic therapy in patients 12 years of age and older.**

Available in **3 strengths 55mcg; 113mcg; and 232mcg of fluticasone propionate** as a dry powder inhaler




- The ArmonAir RespiClick inhaler has a dose counter attached to the actuator. Each device contains 60 doses.
- **Dose is one inhalation BID**
  - Discard the inhaler when the counter displays 0, 30 days after opening the foil pouch or after the expiration date on the product, whichever comes first.
  - **Instruct patients to not open their inhaler unless they are taking a dose. Repeated opening and closing the cover without taking medication will waste medication and may damage the inhaler.**
  - Advise patients to **keep their inhaler dry and clean at all times. Never wash or put any part of the inhaler in water.**




## FDA Updates Metformin Dosing Information 4-8-2016

- The labeling recommendations on how and when kidney function is measured in patients receiving metformin will include the following information: ◦Before starting metformin, obtain the patient's eGFR.
- **Metformin is contraindicated in patients with an eGFR below 30 mL/minute/1.73 m2.**
- **Starting metformin in patients with an eGFR between 30-45 mL/minute/1.73 m2 is not recommended.**
- Obtain an eGFR at least annually in all patients taking metformin. In patients at increased risk for the development of renal impairment such as the elderly, renal function should be assessed more frequently.
- **In patients taking metformin whose eGFR later falls below 45 mL/minute/1.73 m2, assess the benefits and risks of continuing treatment. Discontinue metformin if the patient's eGFR later falls below 30 mL/minute/1.73 m2.**
- **Discontinue metformin at the time of or before an iodinated contrast imaging procedure in patients with an eGFR between 30 and 60 mL/minute/1.73 m2; in patients with a history of liver disease, alcoholism, or heart failure; or in patients who will be administered intra-arterial iodinated contrast.** Re-evaluate eGFR 48 hours after the imaging procedure; restart metformin if renal function is stable.
  - http://www.fda.gov/downloads/Drugs/DrugSafety/UCM494140.pdf

## Empagliflozin – Jardiance New Indication December 2, 2016

- The U.S. Food and Drug Administration today approved **a new indication for Jardiance (empagliflozin) to reduce the risk of cardiovascular death in adult patients with type 2 diabetes mellitus and cardiovascular disease.**
- Based on a post market **Empa Reg Outcome trial of more than 7,000 patients with type 2 diabetes and cardiovascular disease**. In the trial, Jardiance was **shown to reduce the risk of cardiovascular death compared to a placebo when added to standard of care therapies for diabetes and atherosclerotic cardiovascular disease.**

## EMPA-REG OUTCOME Trial

- The **primary outcome (CV mortality, non-fatal MI and non-fatal stroke)**occurred in 490 of 4687 patients **(10.5%) in the pooled empagliflozin group** and in 282 of 2333 patients **(12.1%) in the placebo group** (hazard ratio in the empagliflozin group, **0.86**; 95.02% confidence interval, 0.74 to 0.99; **P=0.04 for superiority**).
  - **ARR = 1.6%, NNT 63**
  - **No significant differences in rates of MI or CVA**
  - **No significant difference with 10 vs. 25 mg doses.**
  - **Death from cardiovascular causes (3.7%, vs. 5.9% in the placebo group; 38% relative risk reduction; ARR = 2.2%, NNT 46**
    - **NEJM on-line 9-17-2015**

## EMPA-REG OUTCOME Trial

- **Hospitalization for heart failure (2.7% and 4.1%, respectively; 35% relative risk reduction)**
- **Death from any cause (5.7% and 8.3%, respectively; 32% relative risk reduction).**
- **Among patients receiving empagliflozin, there was an increased rate of genital infection (1 in 20 or 5%) but no increase in other adverse events.**
  - **NEJM on-line 9-17-2015**

## CVD-REAL Data

**American College of Cardiology 66th Annual Scientific Session 19 March 2017**

- **CV data from a large retrospective international data set including more than 364,000 patients with type-2 diabetes, (87% of whom did not have a history of cardiovascular disease).**
  - mean age 57, 44% females
- **Treatment with SGLT-2 inhibitors reduced all-cause mortality by 51% and risk of hospitalization for heart failure by 39%.**
  - **41.8% of patients were on dapagliflozin, 52.7% on canagliflozin and 5.5% on empagliflozin. (A/Z sponsored the trial)**
  - Results are consistent with the Empa-Reg Outcome Trial

## EMPA-REG OUTCOME Trial: Renal Data

**Microvascular Outcome**

- **The prespecified composite microvascular outcome in the overall trial population occurred** in 577 of 4132 patients **(14.0%) in the empagliflozin group** and in 424 of 2068 patients **(20.5%) in the placebo group**, a **significant RRR 38% ARR 6.5%, NNT=16**
  - **the overall result for this composite microvascular outcome was driven entirely by the renal component** NEJM on-line June 14, 2016

## FDA Drug Safety Update – 6-14-2016

- FDA has **strengthened the existing warning about the risk of acute kidney injury for the type 2 diabetes medicines canagliflozin (Invokana, Invokamet) and dapagliflozin (Farxiga, Xigduo XR).**
  - from March 29, 2013, to October 19, 2015, the **FDA identified 101 cases of acute kidney injury with sufficient detail to confirm the diagnosis and demonstrate a temporal relationship with canagliflozin (73 patients) and dapaglifozin (28 patients). Hospitalization** for evaluation and management of acute kidney injury **was necessary in 96 of the 101 cases, 22 were admitted to the ICU**. The time to onset of acute kidney injury occurred within one month or less of initiating the drug.

## FDA Drug Safety Update – 6-14-2016

- **In the 78 cases reporting drug discontinuation, 56 cases reported improvement, demonstrating reversibility** of this adverse event in a majority of cases.
- **15 patients received dialysis**
- **11 patients did not recover, which included the 4 deaths (2 were cardiac related).**

## FDA Safety Announcement

- [5-15-2015**] The FDA is warning that the SGLT-2 inhibitors: canagliflozin, dapagliflozin, and empagliflozin may lead to ketoacidosis**, a serious condition where the body produces high levels of blood acids called ketones that may require hospitalization.
- Patients should pay close attention for any **signs of ketoacidosis** and seek medical attention immediately if they experience **symptoms such as difficulty breathing, nausea, vomiting, abdominal pain, confusion, and unusual fatigue or sleepiness**.

## FDA Safety Announcement

- **From March 2013 (approval of the first drug in the class) through June 6, 2014, and identified 20 cases of diabetic ketoacidosis (DKA), ketoacidosis, or ketosis were reported**.
  - The **median time to onset of symptoms following initiation of drug therapy was 2 weeks (range 1 to 175 days).** DKA case **presentations were atypical in that glucose levels were only mildly elevated at less than 200 mg/dL in some reports.**
  - The FDA is continuing to investigate this safety issue.

## SGLT-2 Inhibitors and DKA

- A new analysis from Wake Forest, UNC and Duke) found **39 cases of DKA among 11,197 people with prescriptions for SGLT2 inhibitors (74% in patients with Type 2 DM/ 82% C; 15% D and 3% E). Of these, 26 patients had glucose ≤300 mg/dL, with a mean glucose of 266 mg/dL.** Symptoms reported included **nausea and vomiting (49%),** although researchers said "it is unclear if that was a cause, contributor, or consequence of the DKA." Also**, 67% of the patients had some other obvious event such as surgery, an insulin dose reduction, or weight loss.**
- The authors recommend "**a high index of suspicion for DKA in patients taking SGLT2 inhibitors with unexplained malaise or gastrointestinal symptoms and recommend measuring urine or plasma ketones in that setting,"**
  - Diabetes Care 2017 Mar 28 dc162591.

## SGLT-2 Inhibitors and Amputations?

- **4-15-2016 The European Medicines Agency (EMA) has begun a review of the sodium glucose cotransporter 2 (SGLT2) inhibitor canagliflozin (Invokana, Janssen), used to treat type 2 diabetes, after an increase in amputations, mostly of the toe**, was observed in a large ongoing clinical trial of the drug.
- **Cases of lower-limb amputation occurred in both the active drug and placebo groups in the Canagliflozin Cardiovascular Assessment Study (CANVAS), which is the cardiovascular-outcomes trial for this agent and is randomizing just over 4000 type 2 diabetes patients to canagliflozin 100 mg or 300 mg daily or to placebo, slated for completion in 2017 after a mean of 5.7 years.**

## FDA Drug Safety Alert 5-18-2016

- **Canagliflozin (Invokana, Invokamet): Drug Safety Communication - Clinical Trial Results Find Increased Risk of Leg and Foot Amputations**
  - FDA is alerting the public about interim safety results from an ongoing clinical trial that found an increase in leg and foot amputations, mostly affecting the toes.
  - **Patients taking canaglifozin should notify their health care professionals right away if they notice any new pain or tenderness, sores or ulcers, or infections in their legs or feet.**

## New FDA Safety Alert

- **[5-16-2017]: "Based on new data from two large clinical trials, the FDA has concluded that the type 2 diabetes medicine canagliflozin (Invokana, Invokamet, Invokamet XR) causes an increased risk of leg and foot amputations. We are requiring new** warnings, including our most prominent **Boxed Warning**, to be added to the canagliflozin drug labels to describe this risk."
- Before initiating canagliflozin, **consider factors in the patient's history that may predispose them to the need for amputations**, such as a **history of prior amputation, peripheral vascular disease, neuropathy, and diabetic foot ulcers.**
  - **https://www.fda.gov/downloads/Drugs/DrugSafety/UCM558427.pdf**

## CANVAS Trial Amputations

| | Placebo N=1,441 | Canagliflozin 100 mg N=1,445 | Canagliflozin 300 mg N=1,441 | Canagliflozin (pooled) N=2,886 |
|---|---|---|---|---|
| **Patients with an amputation, n (%)** | **22 (1.5)** | **50 (3.5)** | **45 (3.1)** | **95 (3.3)** |
| **Total amputations*** | **33** | **83** | **79** | **162** |
| Amputation incidence rate (per 1,000 patient-years) | 2.8 | 6.2 | 5.5 | 5.9 |
| **Hazard ratio (95% CI)** | — | **2.24 (1.36, 3.69)** | **2.01 (1.20, 3.34)** | **2.12 (1.34, 3.38)** |

* Some patients had more than one amputation

**Amputations of the toe and middle of the foot were the most common; however, amputations involving the leg, below and above the knee, also occurred. Some patients had more than one amputation, some involving both limbs.**

**Canagliflozin combined data 3.3% vs 1.5% placebo; HR 2.12, ARI 1.8%, NNH 56**
**https://www.fda.gov/downloads/Drugs/DrugSafety/UCM558427.pdf**

## CANVAS R Trial Amputations

| | Placebo N=2,903 | Canagliflozin 100 mg (with up-titration to 300 mg) N=2,904 |
|---|---|---|
| Patients with an amputation, n (%) | 25 (0.9) | 45 (1.5) |
| Total amputations* | 36 | 59 |
| Amputation incidence rate (per 1,000 patient-years) | 4.2 | 7.5 |
| Hazard ratio (95% CI) | — | 1.80 (1.10, 2.93) |

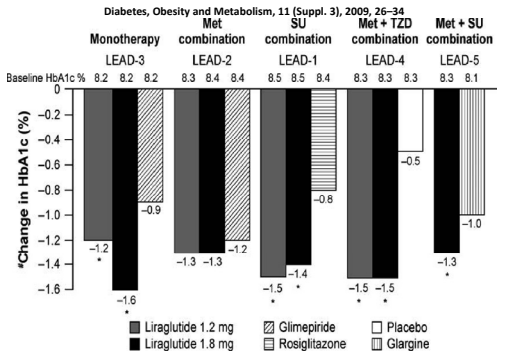
* Some patients had more than one amputation.

**Canagliflozin combined data 1.5% vs. 0.9% with placebo; HR 1.80; ARI 0.6%, NNH 167**
**(This renal safety study was only a mean duration of 2.1 years)**
**https://www.fda.gov/downloads/Drugs/DrugSafety/UCM558427.pdf**

**Liraglutide – Victoza by Novo-Nordisk**

- A human analog of the glucagon-like peptide-1 (GLP-1) with 97% amino acid sequence homology to endogenous human GLP-1.
  - T1/2 ~11-15 hrs
  - **1.2 mg dose (2 pens/mo)**
    - **$497.00 GoodRx.com**
  - **1.8 mg dose (3 pens/mo)**
    - **$743.00 GoodRx.com**
  - Adjunct to diet and exercise for Type 2 DM but not first line and no data in combo with prandial insulin

**Liraglutide with or without oral antidiabetic drug therapy in type 2 diabetes: an overview of the LEAD 1–5 studies**




## Liraglutide – Victoza CV Outcomes

- **LEADER was a multicenter, international, randomized, double-blind, placebo-controlled trial** investigating the long-term effects of **liraglutide (1.2 and 1.8 mg) compared to placebo, both in addition to standard of care**, in people with type 2 diabetes at high risk of cardiovascular events. The trial was initiated in September 2010 and **randomized 9,340 people with type 2 diabetes from 32 countries that were followed for 3.5-5 years.** The primary endpoint was the first occurrence of a composite cardiovascular outcome comprising cardiovascular death, non-fatal myocardial infarction or non-fatal stroke.
  - N Engl J Med 2016; 375:311-322July 28, 2016

## LEADER CV Safety Trial with Liraglutide

- **9340 patients with type 2 diabetes and high cardiovascular risk** to receive liraglutide or placebo. **The primary composite** outcome in the time-to-event analysis **was the first occurrence of death from cardiovascular causes, nonfatal myocardial infarction, or nonfatal stroke.**
  - **The median follow-up was 3.8 years.**
- **The primary outcome** occurred in significantly fewer patients in the **liraglutide** group (608 of 4668 patients **[13.0%]**) than in the **placebo** group (694 of 4672 **[14.9%]**) **(HR 0.87;** 95% CI , 0.78 to 0.97; **P<0.001 for noninferiority; P = 0.01 for superiority) ARR 1.9%, NNT=53**
  - N Engl J Med 2016; 375:311-322July 28, 2016

## LEADER CV Safety Trial with Liraglutide

- **Death from cardio-vascular causes** in the **liraglutide** group (219 patients **[4.7%]**) than in the **placebo** group (278 **[6.0%]**) (hazard ratio, 0.78; 95% CI, 0.66 to 0.93; P = 0.007). **ARR 1.3%, NNT 77**
- The rate of **death from any cause** was lower in the **liraglutide** group (381 patients **[8.2%]**) than in the **placebo** group (447 **[9.6%]**) (HR 0.85; 95% CI, 0.74 to 0.97; P = 0.02). **ARR 1.4%, NNT=72**
  - N Engl J Med 2016; 375:311-322July 28, 2016

## LEADER CV Safety Trial with Liraglutide

- The rates of **nonfatal myocardial infarction (HR 0.88), nonfatal stroke (HR 0.89), and hospitalization for heart failure (HR 0.87) were all nonsignificantly lower in the liraglutide group than in the placebo group.**
  - N Engl J Med 2016; 375:311-322July 28, 2016

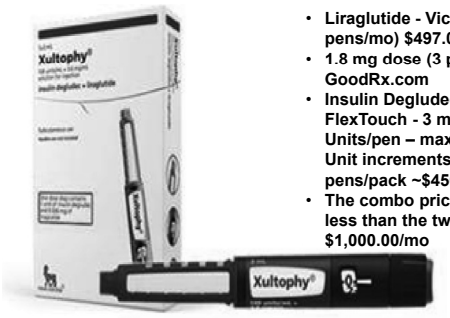
## LEADER CV Safety Trial with Liraglutide

- Microvascular Outcomes: The incidence of a **composite outcome of renal or retinal microvascular events was lower in the liraglutide group than in the placebo group (HR 0.84; 95% CI, 0.73 to 0.97; P= 0.02)**
  - The difference that was **driven by a lower rate of nephropathy events in the liraglutide group (1.5 vs. 1.9 events per 100 patient-years of observation; HR 0.78**; 95% CI, 0.67 to 0.92; P = 0.003)
  - The incidence of **retinopathy events was nonsignificantly higher in the liraglutide group than in the placebo group (0.6 vs. 0.5 events per 100 patient-years; HR 1.15**; 95% CI, 0.87 to 1.52; P = 0.33).
    - N Engl J Med 2016; 375:311-322July 28, 2016

## LEADER CV Safety Trial with Liraglutide

- The **most common adverse events leading to the discontinuation of liraglutide** were **gastrointestinal events**. The incidence of **pancreatitis was non-significantly lower in the liraglutide group (18 vs. 23)** than in the placebo group.
  - **Pancreatic carcinoma 13 (0.3) with liraglutide vs. 5 (0.1) with placebo p=0.06**
  - **Medullary thyroid carcinoma 0 with liraglutide vs. 1 (<0.1) with placebo p=0.32**
    - N Engl J Med 2016; 375:311-322July 28, 2016

## Xultophy (IDegLira) by Novo/Nordisk (combination of insulin degludec/Tresiba plus liraglutide/Victoza)




- **Liraglutide - Victoza:1.2 mg dose (2 pens/mo) $497.00 GoodRx.com**
- **1.8 mg dose (3 pens/mo) $743.00 GoodRx.com**
- **Insulin Degludec- Tresiba U-100 FlexTouch - 3 mL 100 units/mL - 300 Units/pen – max dose 80 Units in 1 Unit increments – available 5 pens/pack ~$450.00**
- **The combo price will be about 20% less than the two separately ~ $1,000.00/mo**

## Insulin degludec plus liraglutide - Xultophy

- **Dosage: adults with type 2 diabetes mellitus inadequately controlled on basal insulin (less than 50 units daily) or liraglutide (less than or equal to 1.8 mg daily) as an adjunct to diet and exercise.**
- **The recommended starting dosage is 16 units (16 units of insulin degludec and 0.58 mg of liraglutide) QD for all patients**
  - **Therapy with basal insulin and liraglutide should be discontinued prior to initiation of Xultophy® 100/3.61**
  - Dose once daily at the same time each day with or without food
  - **If a dose is missed, the patient should resume their once-daily dosing with their next scheduled dose**
  - **If more than three days have elapsed since the last Xultophy® 100/3.6 dose, reinitiate Xultophy® 100/3.6 at the starting dose (i.e., 16 units) to mitigate any gastrointestinal symptoms**

## Insulin degludec plus liraglutide - Xultophy

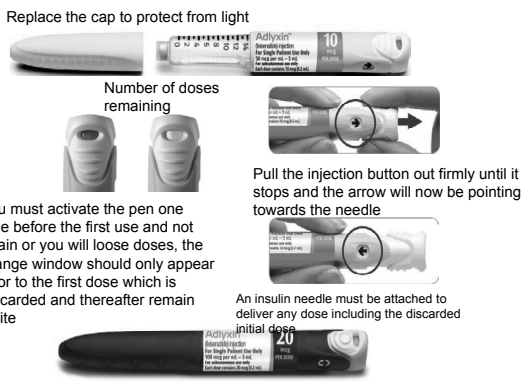
- **Dose Titration:**


- The **label recommends that the patient titrate the dose up or down by 2 units every 3 to 4 days based on self-monitored FPG** until the desired FPG is achieved (IE. 80-130 mg/dl?)
- The **maximum daily dosage is 50 units (50 units of insulin degludec and 1.8 mg of liraglutide)**
- If **persistent dosages below 16 units or above 50 units are required, discontinue and use alternative therapy** (including the two components separately IE max dose of liragultide (1.2 vs. 1.8 mg?) plus whatever dose of basal insulin required).
- **Cost: 5 x 3 ml U100/3.6 mg pens $1,020.00**

## Lixisenatide – Adlyxin by Sanofi

- **FDA approved 7-27-2016 a once a day GLP-1 receptor agonist** indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
  - **Injection: 50 mcg/mL in 3 mL in green prefilled pen (for 14 pre-set doses; 10 mcg per dose)**
  - **Injection: 100 mcg/mL in 3 mL in burgundy prefilled pen (for 14 pre-set doses; 20 mcg per dose)**
    - **Cost: ~$600.00/ 2 pens (28 day supply)**
  - **Initiate at 10 mcg once daily for 14 days. On Day 15, increase dosage to 20 mcg once daily**
    - Administer once daily within one hour before the first meal of the day

## Lixisenatide – Adlyxin

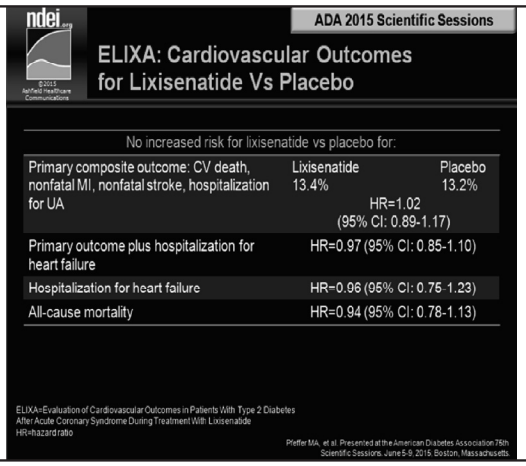



## Lixisenatide vs. Liraglutide

- **26-week**, randomized, parallel-group, open-label trial, **404 patients were randomized 1:1 to liraglutide 1.8 mg or lixisenatide 20 µg as add-on to metformin**. Liraglutide was administered once daily at any time of the day. Lixisenatide was administered once daily within 1 h prior to the morning or evening meal.
- At week 26, **liraglutide reduced HbA1c (primary end point) more than lixisenatide (estimated treatment difference −0.62%** [95% CI −0.8; −0.4]; P < 0.0001), with more patients reaching HbA1c <7% and ≤6.5% versus lixisenatide (74.2% and 54.6% for liraglutide vs. 45.5% and 26.2% for lixisenatide; P < 0.0001 for both).
- Both drugs promoted **similar body weight decrease (−4.3 kg for liraglutide, −3.7 kg for lixisenatide; P = 0.23).**
  - Diabetes Care 2016 Sep; 39(9): 1501-1509.

## ELIXA – a cardiovascular safety outcomes trial of lixisenatide

- **Lixisenatide (Adlyxin)was FDA approved 7/28/2016**
- March 2015, Sanofi announced top-line results of the ELIXA outcome study, a **Phase IIIb cardiovascular safety outcomes trial of lixisenatide (Adlyxin®) compared to placebo in 6,000 a high-risk (post ACS) population of adults with Type 2 diabetes** for the evaluation of cardiovascular safety.
  - **First CV safety trial for any of the GLP-! Agonists to report out.**
- The results from the study showed **that lixisenatide was non-inferior, although not superior, to placebo for cardiovascular safety**, and establish that there is no additional cardiovascular risk, in a high-risk patient, associated with treatment with lixisenatide, helping to support the existing consensus around the therapeutic benefits of lixisenatide.
  - Results presented at ADA in Boston on June 9, 2015




### Soliqua™ 100/33 (insulin glargine & lixisenatide injection) 100 Units/mL & 33 mcg/mL

- **Soliqua 100/33 will be delivered in a single pre-filled pen for once-daily dosing covering 15 to 60 Units of insulin glargine 100 Units/mL and 5 to 20 mcg of lixisenatide using SoloStar** technology, Soliqua 100/33 will be available in U.S. retail pharmacies in January 2017.

**Price ~$680.00/5 pens GoodRx.com 1-25-2017**

## Soliqua™ 100/33 (insulin glargine & lixisenatide injection) 100 Units/mL & 33 mcg/mL

**Dosage and Administration:**

- Discontinue therapy with lixisenatide or basal insulin prior to initiation of Soliqua 100/33.
- **In patients inadequately controlled on less than 30 units of basal insulin or on lixisenatide, the starting dosage is 15 units (15 units insulin glargine/5 mcg lixisenatide) given subcutaneously once daily.**
- **In patients inadequately controlled on 30 to 60 units of basal insulin, the starting dosage is 30 units (30 units insulin glargine/10 mcg lixisenatide) given subcutaneously once daily.**
- Inject once a day within the hour prior to the first meal of the day.
- **Maximum daily dosage is 60 units (60 units of insulin glargine and 20 mcg of lixisenatide).**
- Soliqya 100/33 **Pen delivers doses from 15 to 60 units with each injection.**

## Insulin Glargine – Basaglar by Lilly and BI

- **Dec 16, 2015 FDA approved Basaglar (insulin glargine) but not launched until after Dec 2016 based upon court action. T**he first insulin product approved through an abbreviated approval pathway under the FDA 505(b) (2) application which did rely partly on the safety and effectiveness of Lantus (insulin glargine by Sanofi).
- **Lilly just announced the price will be ~15% lower than Lantus**
- **Cost: ~$343.00 per box of 5 pens vs. Lantus $403.00 per box of 5 pens**

The FDA determined that Basaglar was sufficiently similar to Lantus and in addition Basaglar was studied in two large trials (543 Type 1 and 744 Type 2 patients with diabetes). Like Lantus FDA approved for patients age 6 and up.

**Basaglar is considered a "follow-on" NOT FDA approved as a "Biosimilar" product. (There is no reference listed drug for Lantus under the Public Health Services Act)**

## Insulin Glargine U100 – MK1293
### by Merck/Samsung Bioepis

- **Merck has also filled for FDA approval 8/2016 for U 100 insulin glargine** known as MK1293. In **two phase 3 trials MK-1293 achieved its primary endpoint by demonstrating non-inferiority in change from baseline A1C and similar safety to Lantus® (insulin glargine) after 24 weeks in patients with type 1 and type 2 diabetes.**
- As with Lilly's Basaglar, Sanofi is expected to also file a patent infringement suit against Merck and Samsung if their biosimilar nears registration, prompting an immediate 30-month injunction on launch.

## Insulin Glargine U100 by Mylan/Bioepis

- **Mylan and Biocon Ltd (India's largest biopharmaceutical Co.) announced that the European Medicines Agency (EMA) in Nov 2016 has accepted for review Mylan's Marketing Authorization Application (MAA) for insulin glargine**, a long-acting insulin analog used to treat adults with type 2 diabetes and adults and pediatric patients (children 6 years and older) with type 1 diabetes for the control of high blood sugar.
  - Biocon and Mylan are exclusive partners on a broad portfolio of biosimilars and insulin analogs. **Glargine is one of the three insulin analogs (lispro and aspart) being co-developed by Mylan and Biocon for the global marketplace**. Mylan has exclusive commercialization rights for insulin glargine in the U.S., Canada, Australia, New Zealand, the European Union and European Free Trade Association countries.
  - Biocon has exclusive rights for Japan and a few emerging markets; and co-exclusive commercialization rights with Mylan in the rest of the world.

SELF EVALUATION

## Pharmacotherapy Update - Parts 1 & 2

### True/False

**1.** The new Zoster sub-unit vaccine which is pending FDA approval, appears to be about 90% effective and unlike the current vaccine is not a live attenuated vaccine but it is given as a 2 dose series at 0 and 2 months.

**2.** In 2016 the CDC recommended against the use of the live attenuated nasal flu vaccine, because in the 2015 flu season it was not any more effective than placebo (~3%) in children ages 2-17 years of age.

**3.** According to the CDC and the WHO, the 2016-17 flu season vaccine A and B strains are about 50% susceptible to the recommended antivirals as of Feb 2017.

**4.** According to the FDA the new HPV-9 vaccine (Gardasil-9), has the potential to prevent ~90% of cervical, vulvar, vaginal and oral cancers.

**5.** The CDC has recommended HPV-9 vaccine (Gardasil-9) to all 15-16 year olds as a two dose series at least 6 months apart.

**6.** The CDC has modified its recommendation for Tdap in pregnancy, to prefer the dose be administered as close to delivery as possible (IE. 36 weeks).

**7.** The CDC has modified its recommendations for hepatitis B vaccine to include' the first dose should now be administered to all newborns in the first 24 hours after birth.

**8.** The American Assoc of Clinical Endocrinologists and the American College of Endocrinologists have updated their Lipid Guidelines to include a new category called "Extreme Risk" with an LDL-C goal of </= 55 mg/dl.

**9.** Of the two FDA approved PCSK-9 inhibitors alirocumab –Praluent and evolocumab – Repatha, only alirocumab has data and FDA approval for the treatment of patients with homozygous Familial Hypercholesterolemia.

**10.** In March 2017 during the American College of Cardiology Annual Meeting, the results of the first CV outcomes trial with any PCSK-9 inhibitor were presented and evolocumab – Repatha in the FOURIER Trial, produced a significant reduction in both non-fatal MI and non-fatal stroke when added to moderate/high intensity statin with or without ezetimibe.

**11.** According to the 2017 GOLD Guidelines for patients with COPD, most of the 11 million US COPD patients should be receiving dual long-acting bronchodilators with a LAMA/LABA.

**12.** According to the 2017 GOLD Guidelines, patients with COPD can be treated with inhaled corticosteroids as mono-therapy and they do not appear to increase the risk of pneumonia.

**13.** Currently the only FDA approved once a day ICS/LABA is fluticasone furoate/vilanterol known as Breo Ellipta.

**14.** Currently we have 3 FDA approved formulations of tiotropium: including Spiriva Handi-haler for COPD; Spiriva Respimat for COPD; and Spiriva Respimat for asthma and all three are dosed once a day.

**15.** The 2017 American Assoc of Endocrinologists and American College of Endocrinologists Guidelines for the treatment of patients with Type 2 Diabetes prefer metformin followed by a GLP-1 agonist, then an SGLT-2 inhibitor, based upon A1c reductions, lack of weight gain and low risk of hypoglycemia.

**16.** As a class both the GLP-1 agonists and the SGLT-2 inhibitors have been shown to reduce CV events in all of the current clinical trials.

**17.** The Empa-Reg Outcome Trial with the SGLT-2 inhibitor empagliflozin – Jardiance has demonstrated a significant reduction in CV mortality as well as non-fatal MI and non-fatal stroke.

**18.** In May 2017 the FDA added a "Black-Box Warning" to the label of canagliflozin – Invokana based upon data from the CV outcome CANVAS Trial which found about a doubling of the risk of lower extremity amputations in patients taking canagliflozin.

**Answer Key:** 1. T, 2. T, 3. F, 4. T, 5. F, 6. F, 7. T, 8. T, 9. F, 10. T, 11. T, 12. F, 13. T, 14. T, 15. T, 16. F, 17. F, 18. T

## Andrew M. Knoll, MD, JD

Andrew M. Knoll, MD, JD, of Syracuse, New York, is a partner and co-founder of Cohen Compagni Beckman Appler & Knoll, PLLC, a boutique, nationally recognized healthcare firm. He is a 2003 summa cum laude graduate of Syracuse University College of Law, where he was an editor of *Syracuse University Law Review* and received the *Justinian Society Award for Highest Academic Average*. A former emergency physician and hospitalist, Dr. Knoll was board certified in internal medicine for twenty years and previously a fellow of the American College of Physicians. He is also a Persian Gulf veteran and former Navy flight surgeon achieving the rank of commander in the United States Naval Reserve.

You may contact Dr. Knoll with your questions or comments at (315) 477-6241, or by email at aknoll@ccblaw.com.

ccb LAW

**Medical Malpractice Anatomy - Parts 1 & 2**
***Andrew M. Knoll, MD, JD***

## Disclaimer

- This presentation is for educational purposes only and does not constitute legal advice or counsel nor does it create an attorney-client relationship

## Overview & Goals

- Overview
  - Professional liability insurance
  - The four elements of a claim for malpractice
  - Timeline for a typical malpractice lawsuit
- Goals
  - Understand the types of malpractice insurance and financial ramifications of same
  - Understand the important elements of a malpractice claim and how that relates to your potential liability to a patient
  - Be familiar with the typical course of a medical malpractice case
  - Be familiar with the after effects of being held liable or settling a case

## Professional Liability Policies, cont.

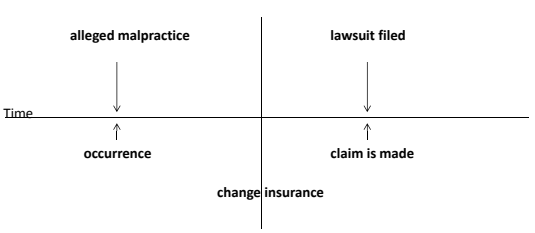
- Commercial insurance
  - Single state
  - National (often specialty based: anesth., psych)
- Risk Retention Groups
- Entity Self Insured (e.g., Kaiser Permanente)
  - Captive insurance companies
  - Excess with Lloyds
- Federal Tort Claims Act (FTCA)

## Professional Liability Policies

- Limits vary based on jurisdiction
  - NY: typically $1.3M/$3.9M, with excess coverage of $1 M if have hospital privileges
  - FL: often uncovered, $250K-1M
  - CA, IL: $1M
  - Commonest: $1M

## Professional Liability Policies

**Occurrence vs. Claims' Made Policies**




**A "tail" converts a Claims' Made policy to an Occurrence policy**

## Statute of Limitations

- Period of time between when the case "accrues" and is "imposed", after which is time barred
- Typically vary from 2 years (Tx) to 3 years (CA)
- Discovery jurisdictions
  - When plaintiff discovers, or through the use of reasonable diligence should have discovered the injury
  - CA, FL, IL
  - Some are capped (FL & IL: 4 yrs)

**COHEN COMPAGNI BECKMAN APPLER & KNOLL, PLLC**
Attorneys and Counselors at Law
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## SOL Extensions

- Minors –
  - NY up to 10 years
  - CA child under 6 is 3 yrs or before 8th b-day (FL too)
- Continuous Treatment Doctrine
- Foreign Bodies (e.g., NY 1 year after know or should have known)
- Fraud or concealment
  - NY common law
  - FL, CA statutory

## Law 101

- Elements of Negligence
  - Duty
  - Breach
  - Cause
  - Damages
- Elements of Malpractice
  - Duty = Physician-Patient relationship
  - Breach = Deviation from the Standard of Care
  - Damages = Injury (with resultant damages)
  - Causation – did the deviation from the Standard of Care "cause" the injury?

## Physician-Patient Relationship

- General Rule – created when professional services are rendered and accepted for purposes of diagnosis and medical treatment
  - direct, personal relationship
- Modern Variations
  - implied physician-patient relationship
  - limited duty
  - duty to third persons

## Implied Physician Patient Relationship

- Contractual
  - On call for group or ED
  - Other agreements to provide coverage
- Supervisory
  - Residents
  - Non-Physician Practitioners (e.g., NP, PA)
- "Curbside consult"

## Limited Duty

- Employment exams, IME
- Cannot harm the patient
- Duty to advise of recognized conditions

## Duty to Third Persons

- Issue: when does a physician's duty extend to a non-patient, such that the non-patient can sue the doctor for injuries caused by the doctor's patient?
- Identified vs. the public at large
- Very jurisdictionally specific
- Generally a duty to warn
  - The patient?
  - The third party?

## Duty to Third Persons – Identified

- "Identified" means a specific person
- *Tarasoff v. The Regents of the Univ. of Cal*., 17 Cal.3d 425 (Cal. 1976)
  - duty to warn (satisfied by notifying the authorities)
  - foreseeable and serious harm
  - HIPAA permits (45 CFR 164.512(j))
- Family Members
  - *Tenuto v Lederle Labs*, 90 N.Y.2d 606 (N.Y. 1997) (duty to foreseeable family members)
  - Genetic testing and conditions (e.g., BRCA, familial polyposis
  - Majority rule is duty satisfied by telling the patient

## Duty to Third Parties – Unidentified

- Question is whether the duty of care owed by the physician to a patient extends to the general public when one of them is hurt by the patient
  - Typically MVA cases
- Prescribed or Administered Medications
  - Evolving area of the law, with more jurisdictions extending the duty to the general public
- At risk medical conditions
- The duty is satisfied by warning the patient

## Guidelines regarding Duty to the General Public

- Reiterate that rules are very State specific
- When the physician knows, either through testing or the condition, that the patient's condition gives rise to a risk to a family member, physician has the duty to warn *the patient* that relatives are at risk and should be tested
- A physician who administers or prescribes an impairing drug may have a duty to warn *the patient* about driving or other risky conduct to others
- A physician who is aware that the patient has an impairing condition has a direct duty to the patient to warn, but majority rule is it doesn't extend to the general public

## Deviation from the Standard of Care

- Prudent physician standard
  - Logistics rule
- Guidelines
  - Not a *per se* SOC
  - Practically, persuasive and may establish a presumption
  - Expressly document reasoning if knowingly deviate
- Requires expert testimony
  - Exception: *Res ipsa loquitor*
    - Foreign bodies
    - Anesthesia nerve palsies
- Why malpractice does not regulate quality
  - Battle of the experts
    - Pneumoconiosis example
  - Skill of the lawyer

## Injury

- Must be damages
- Economic losses
  - Lost wages
  - Medical expenses – collateral source rule and liens
  - Replacement services
- Non-economic damages
  - Pain and suffering
  - Loss of consortium

## Injury – Economic Caps

- Only on non-economic damages
- TX $250,000
- FL $500,000
- IL statute rules unconstitutional in *LeBron v. Gottlieb Memorial Hospital* (2010)

## Causation

- "But for" – would not have been injured "but for" the negligence of the tortfeasor
- "Substantial factor" – the tortfeasor's negligence was a "substantial factor" in causing the injury
- "Lost Chance" doctrine
  - Usually missed diagnosis cases
  - Also factors in determining damages

## Miscellaneous Issues

- Lack of informed consent
  - Objective vs. subjective
- Wrongful life – birth, right-to-die
- Entity liability
  - Direct – negligent credentialing
  - Vicarious – employees, ostensible agency and non-delegable duties (*Mduba* Doctrine)

## Typical Timeline

- Something bad happens
  - Starts the clock for the Statute of Limitations
  - Consider notifying malpractice carrier
- Attorney request for medical records
  - Definitely notify the carrier
- Time goes by . . .

## Timeline, cont.

- Service of Summons & Complaint
  - Tone varies from professional to inflammatory
  - Alternative: receipt of a demand letter
- Technically, usually a short period of time to Answer a S&C if served personally
- DON'T talk to opposing counsel
- IMMEDIATELY call the carrier
  - Assign counsel
  - Counsel will get an extension and serve an Answer

## Timeline, cont.

- Discovery
  - Document production
  - Depositions
    - Oral questioning under oath
    - Do not try to win your case
    - LISTEN TO YOUR LAWYER
  - Interviewing or deposing subsequent treating physicians

## Timeline, cont.

- Upon completion of discovery, either side may file for summary judgment
- Notifying the court that the case is trial ready and placing on the docket
- Consider settlement

## Timeline, cont.

- Trial
- Plaintiff goes first; may call the physician as an adverse witness
- Battle of the Experts
- If not settled, decided by trier or fact

## Timeline, cont.

- Post-trial motions
- Appeal
- Aftermath
  - None if "no cause"
  - NPDB if lose
- In my 30+ year medical and legal career I have never personally heard of anyone involuntarily paying out of pocket for an insured malpractice claim

SELF EVALUATION

**Medical Malpractice Anatomy - Parts 1 & 2**

**True/False**

**1.** The two categories of professional liability insurance are: claims made and occurrence.

**2.** In addition to commercial insurance, other forms of professional liability coverage include risk retention groups, entity self-insurance and Federal Tort Claims Act (FTCA).

**3.** The period of time between when a malpractice case accrues and it must be sued in order to be timely is called the Statute of Restriction.

**4.** The elements of a malpractice claim are duty, breach, causation and damages.

**5.** A physician/patient relationship is created when professional services are rendered and accepted for purposes of diagnosis and treatment.

**6.** Physician relationships may be direct or implied.

**7.** Physicians never owe a duty to individuals who are third parties, i.e., people who are not the physician's patient.

**8.** A doctor who gives a "curbside consult" cannot be sued for the advice that was given.

SELF EVALUATION

**Medical Malpractice Anatomy - Parts 1 & 2 cont.**

**9.** Generally, a physician who gives a patient an impairing drug or knows of a condition that could lead to incapacity while driving (e.g., uncontrolled epilepsy) has a duty to warn the patient that he/she could injure someone.

**10.** A guideline is absolute evidence of the standard of care in the area addressed by the guideline.

**11.** *Res ipsa loquitor*, the "thing speaks for itself," may apply in cases of retained foreign bodies or nerve palsies following surgery.

**12.** Injury in a medical malpractice lawsuit is generally divided into two categories: economic damages and non-economic damages.

**13.** States that have capped damages cap both economic and non-economic damages.

**14.** The "Lost Chance" doctrine refers to a procedural mistake made by the defense medical malpractice attorney.

**15.** An entity such as a hospital can only be held vicariously liable for its employed physicians, and not physicians on the medical staff who are not employees.

**16.** When served with a Summons & Complaint, there is no immediacy. The physician can take his/her time in notifying the carrier and finding a lawyer.

**17.** A deposition is the time for a physician to vigorously defend himself against the plaintiff medical malpractice attorney who is conducting the deposition.

**18.** Even if the physician prevails at trial, there will be a report filed with the National Practitioners Database (NPDB).

**Answer Key:** 1. T, 2. T, 3. F, 4. T, 5. T, 6. T, 7. F, 8. F, 9. T, 10. F, 11. T, 12. T, 13. F, 14. F, 15. F, 16. F, 17. F, 18. F

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## Reasoning with Unreasonable People

Difficult conversations are inevitable in the helping professions. Telling a patient something they don't want to hear; confronting a colleague who's letting you or a patient down; saying "no" to a patient or family member's request; handling a complaint; giving an unwelcome instruction or suggestion to a patient, colleague or supervisee; and saying "no" to a supervisor's unreasonable expectation are but a few of the challenging situations that may confront the healthcare professional on a regular basis. Complicating any of these situations further is our own formidable resistance to engaging the other person. We want to protect ourselves from attack, or at least from embarrassment; we may not have a great track record for handling interpersonal conflict; we procrastinate because of anxiety, fear, fatigue and a host of other reasons; and we worry about making the situation worse if the conversation were to go terribly wrong, e.g., retaliation from the other person.

In this program, healthcare professionals will learn several strategies for communicating with difficult, challenging patients. Research indicates that the most challenging of people are those who have problems with irrational thinking, emotional dysregulation and/or impulse control. These disorders include: major mood disorders, obsessive-compulsive disorder (OCD), pathological anger, anxiety-based disorders and personality disorders.

As a result of completing this program, participants will be able to:

1. Discuss the symptoms and problematic beliefs associated with major depression, bipolar spectrum illness, anxiety-based disorders, OCD, anger mismanagement and selected personality disorders.

2. List effective pathways to reasoning with the highly emotional or otherwise unreasonable patient.

3. Describe and practice six key strategies for handling especially difficult conversations with these patients and their families.

I. <u>Unreasonable People: Core Characteristics</u>

   A. They generally operate from a set of core beliefs (schema) that are irrational or otherwise problematic. These problematic beliefs are typically learned in childhhod or adolescence and are highly resistant to change. (See Appendix A.)

   B. They have major problems with managing their emotions, most especially anxiety and anger.

   C. They precipitate conflict and many even thrive on it.

   D. They are highly impulsive/reactive individuals; they act without thinking about the consequences of their behavior.

   E. They exercise poor judgement. They typically have poor insight and rarely learn from their mistakes.

   F. When confronted with their UNWISE behavior, they will react defensively by, for example, attacking the other person. They also project blame/responsibility for their problems onto others.

   G. They typically meet diagnostic criteria for one or more major psychiatric illnesses.

II. Pathways to Effective Reasoning

A. Assuring that the person feels heard.
   1. Active Empathic Listening
   2. Emotional healing begins when the patient's feelings, observations and concerns are validated by the healthcare provider.

B. Focus on feelings.
   1. What are the patient's emotional triggers/suppressors?
   2. What feelings get triggered, e.g., anger?
   3. What does the patient currently do to calm/soothe themself once triggered?

C. Focus on beliefs/schema.
   1. What core beliefs are being triggered?
      "I'm not good enough."
      "I'm being abandoned."
      "I'm entitled."
   2. What makes these beliefs so compelling?
      Reinforced by parents/peers?
      Maintain patient's identity?
   3. What can be done to challenge/change these beliefs?
      Cognitive-behavioral psychotherapy?
      Thought-stopping?
      "Where's the evidence/data to support this belief?
      "Is there evidence to support an alternative way of thinking about this situation?
      "Can I change my narrative?"

D. Identify the patient's core strengths:
   1. Resilience
   2. Intrapersonal skills, e.g., self-soothing, distracting techniques
   3. Interpersonal skills, e.g., easily connects with others in a group such as AA or
   4. NA group
   5. Emotion regulation skills:
      deep breathing; use of imagery
      counting slowly from 1 to 10
      the ice-cube strategy
      waiting 24 hours before expressing anger

E. Core emotional concerns:
   1. To feel understood
   2. To feel appreciated
   3. To be given the benefit of the doubt
   4. To be treated as an equal

5. To be treated respectfully
6. To have the freedom to decide

F. Beyond reason:

1. Rage
2. Acute mania
3. Delirium
4. Substance-induced states
5. Psychosis
6. Dementia/Organic Brain Syndrome

III. Model for Handling Especially-Difficult Conversations (Back, 2002, 2005, 2005)

A. State your positive intent.

1. Explain your purpose, highlighting the benefit to the other person.
2. Helpful for intent to convey empathy or to affirm other person in some way.

B. Tell the truth fast.

1. Get to the point quickly.
2. Be factual and specific.
3. Explain impact; i.e., negative consequences.

C. Listen and understand.

1. Invite reactions and inquire.
2. Listen intently; acknowledge the other person's feelings.
3. Check your understanding.

D. Find common ground.

Summarize your shared interest or goal. e.g., "We both want…"

E. Identify options and your action plan.

1. Identify possible courses of action and the pros and cons of each.
2. Agree on your approach – a plan of action for both of you.

F. Express appreciation.

1. Convey positive regard, i.e., thanks, admiration or appreciation. e.g., "This wasn't easy, and I appreciate your openness…"
2. "How are you feeling about our conversation…?"

G. Trouble-shooting:

1. Beforehand, adopt a positive mindset, or at least a neutral one. Do not come across as frustrated, angry or blaming. Be respectful and open.
2. If the person resists:

Empathize with resistance.

Repeat steps "A" through "F" in the face of continuing resistance.

3. If you're on the receiving end, open your mind.

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## Appendix A: Problematic Core Beliefs (Schema)

A. These core beliefs are called "schema." A schema is an extremely stable and enduring patterns of thinking that is learned in childhood or adolescence. We view ourselves, others and the world around us through our schema.

B. Research has revealed 16 specific types of problematic schema (Young, 1990):

1. Dependence/Incompetence

   "I'm not able to handle day-to-day responsibilities independently or competently."

   "I must rely on others to take care of me because I am so inadequate/incompetent."

2. Subjugation

   "I must defer to the advice, opinion and control of others to avoid negative consequences."

   "I must ignore my own observations, desires and feelings and focus exclusively on those of others."

3. Self-sacrifice

"I must always focus on the needs of others; to do otherwise will make me feel guilty."

"Putting others first makes me feel useful/valid."

4. Vulnerability to Harm or Illness

   "I am always vulnerable to a major catastrophe (financial, medical, emotional, etc.)."

   "I must always take extraordinary precautions to protect myself."

5. Fear of Losing Control

   "If I'm not careful, I will lose control over my own behavior, impulses, feelings, mind, body, self."

   "To show strong emotion is losing control."

6. Emotional Deprivation

   "I will never meet anyone who truly cares about me."

   "My needs, feelings, expectations will never be fulfilled in a relationship; I am destined to be alone."

7. Abandonment/Loss

   "All of my relationships are doomed to failure."

   "Anyone who cares about me will ultimately abandon me."

   "To be alone is to be abandoned."

8. Defectiveness/Unloveability

   "I am a terribly damaged, flawed person."

   "When others get close to me, they will see my flaws and ultimately reject me."

9. Mistrust/Abuse

   "Others will intentionally betray or otherwise take advantage of me."

   "Don't let others get close. They will see my vulnerabilities and use this to hurt me."

   "Be wary of anyone who has power; they will use it to harm me in some way."

10. Social Isolation/Alienation

    "I am so different from others that they could never accept me."

    "I am so clearly superior to others that they could never meet my expectations."

11. Social Undesirability

    "I am so physically unattractive, inept, stupid and unpopular that no one would ever want to be with me."

12. Shame/Embarrassment

    "I possess certain characteristics that are both unacceptable and easily detected by others. I will always be seen as "less than" because of these characteristics."

    "There is something fundamentally wrong with me or my family. I must always try to keep this hidden from others."

13. Perfectionism

    "Whatever I do isn't good enough."

    "Status, wealth, power trump all other values."

    "Failure is unacceptable."

14. Failure to Achieve

    "I am incapable of performing as well as my peers in <u>any</u> arena."

"What's the point of trying? I will always fail."

15. Self-Punishment

"I deserve to be treated harshly because I am such a disappointment to others."

16. Insufficient Limits/Entitlement

"I should be able to do or say whatever I want."

"I am more special than you. Therefore, I deserve special treatment always."

"I shouldn't have to play by the rules because I am so special/superior."

C. What makes schema so compelling?

1. We learn them as a result of interacting with major players in our life, most especially parents and significant peers.
2. Real life experiences can reinforce any belief making it more resilient.
3. We can distort reality such that it conforms with core schema, e.g.; negative interpretations and predictions of life events.
4. We can highlight or exaggerate information that conforms to the core schema, e.g., "Everyone in my class hated me."
5. We will engage in behaviors that confirm a deeply-held albeit distorted belief, e.g., "No one likes me." can lead to social isolation and withdrawal.
6. We will avoid situations that trigger painful schema, e.g., not accepting a promotion at work due to a core belief regarding "failure".

D. Rigidly-held beliefs (schema) cause problematic behaviors and negative emotions.

e.g., If you believe that you are always entitled to special treatment, you will behave in an aggressive, self-centered fashion. This will likely alienate, annoy or intimidate others. This increases the likelihood that others will not be all-that-interested in meeting your needs/expectations. Their "failure" to meet your needs will likely trigger anger and frustration in you.

E. Mentally-ill people typically hold an inordinately-high number of irrational or otherwise problematic schema. These problematic schema lead to especially pathological behavior which presents special challenges to the health care professional.

## Appendix B
## Active Listening Skills: Tips

1. Face the speaker.
2. Maintain eye contact.
3. Remain relaxed and calm.
4. Be attentive.
5. Be open-minded and flexible.
6. Listen to the words for meaning.
7. Summarize what the person says.
8. Watch the person's body language for clues.
9. Be aware of your body language.
10. Refrain from interrupting.
11. Wait for the person to pause before speaking.
12. Ask clarifying questions.
13. Don't judge the other person.
14. Try to understand what the person is feeling and validate that.
15. Use statements like, "I understand how you feel" or "I get it".

SELF EVALUATION

## Reasoning with Unreasonable People

**1.** "Unreasonable people" can include which of the following?

a. People who show poor judgement
b. People who have problems with impulse control
c. People who have difficulty regulating their emotions, especially anger
d. All of the above

**2.** Which of the following is not a psychiatric condition associated with unreasonable behavior?

a. Borderline personality disorder
b. Bipolar spectrum illness
c. Avoidant personality disorder
d. Anxiety-based disorders

**3.** Which of the following is not a type of problematic schema?

a. Dependence/Incompetence
b. Subjugation
c. Vulnerability to harm or illness
d. All of the above are types of problematic schema.

**4.** The problematic schema "Mistrust/Abuse" involves all but which of the following?

a. "Others will intentionally try to betray or otherwise take advantage of me."
b. "Be wary of anyone who has power; they will use it to harm me."
c. "I must destroy anyone that I come to trust."
d. "Don't let others get close; they will see my vulnerabilities and use this to hurt me."

**5.** A person who has insufficient limits and a sense of entitlement:

a. Believes they are more special than you.
b. Believes they always deserve special treatment.
c. Believes they don't have to play by the rules because they are so special.
d. All of the above

**6.** Anger management problems include all but which of the following?

a. Assertiveness
b. Chronic passivity
c. Inappropriate aggressive behavior
d. Chronic passive-aggressiveness

**7.** Which of the following is a pathway to effective reasoning?

a. Assuring that the person feels heard
b. Focus on the other person's feelings.
c. Focus on the other person's beliefs/core schema.
d. All of the above are effective pathways.

**8.** Which of the following is not a recommended strategy for dealing with highly emotional patients?

a. Validate their feelings.
b. Engage them in cognitive restructuring.
c. Encourage a diet rich in carbohydrates and fats.
d. Teach them to practice specific breathing techniques.

**9.** Active empathic listening skills include which of the following?

a. Facing the patient and making appropriate eye contact.
b. Refraining from interrupting the patient
c. Attending to the patient's non-verbal behavior
d. All of the above are empathic listening skills.

**10.** Which of the following statements about unreasonable patients is not true?

a. They tend to act/speak before they think.
b. They have a low risk of being manipulative, volatile and litigious.
c. They are typically mentally ill and in denial about this.
d. They often have a history of treatment non-compliance.

**ANSWER KEY:** 1. D, 2. C, 3. D, 4. C, 5. D, 6. A, 7. D, 8. C, 9. D, 10. B

## Josh Umbehr, MD

Josh Umbehr, MD, of Wichita, Kansas, is a practicing, board-certified family physician. He is the founder and principal of Atlas MD a medical practice utilizing a direct patient care model, a subject on which Dr. Umbehr is a nationally recognized thought leader and presenter having spoken and testified numerous times across the country.

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# Direct Patient Care: Understanding the Model

*Josh Umbehr, MD*

## Direct Patient Care Checklist

- **1. Name**
  - ☐ Pick a business name
  - ☐ Check name availability through your state's website > business center > business entity formation
  - ☐ Domain - Enom, Godaddy, Max.d
  - ☐ Domain specific emails - Outlook, Gmail or Other See attached files...
  - ☐ Website - Entermotion, Empoweredmds or Other See attached files...
  - ☐ Social Media - Facebook and Twitter - make sure all info and settings are complete

- **2. Accountant**
  - ☐ Use ours - Reid Hash 785-272-4484 OR r.hash@ssccpas.com
  - ☐ Find Local

- **3. Lawyer**
  - ☐ Use ours - Luanne Leeds See attached files...
  - ☐ Find Local
  - ☐ Create Patient Agreement
  - ☐ Create Privacy Policy >> https://termsfeed.com/privacy-policy/generator/?utm_expid=97203325-254.cWlbs1lcQzO_5W3XmaVodA.0&utm_referrer=https%3A%2F%2Ftermsfeed.com%2Findex2

- **4. ESTABLISH BUSINESS ENTITY**
  - ☐ a. Become certified with your State Medical Board http://www.fsmb.org/state-medical-boards/contacts
  - ☐ Check state regulation if CLIA certification is required > http://www.kdheks.gov/lipo/clia_survey_and_cert.htm
  - ☐ b. Apply for business structure LLC vs PLLC vs S Corp vs C Corp
  - ☐ c. Apply for Federal Tax ID
  - ☐ d. Apply for State ID
  - ☐ Consider completing a small business workshop. Our local college offers a 4 week course for $75. Show the bank a certificate of completion of that course to lower your risk and get better rates, etc.

**Direct Patient Care Checklist**

- **5. Insurance Contracts**
  - ☐ Cancel Medicare See attached files...
  - ☐ Cancel Private Plans

- **6. Location**
  - ☐ Rent, own or lease
  - ☐ Add yourself to www.iamdirectcare.com and iwantdirectcare.com maps

- **7. Coversion**
  - ☐ Determine Schedule - 4/8/12 week timeline
  - ☐ Letters - 1st, 2nd, 3rd See attached files...
  - ☐ Town Halls - Timing, set up, cost

- **8. Marketing**
  - ☐ Word of Mouth
  - ☐ Flyers See attached files...
  - ☐ Radio
  - ☐ Facebook - check the "services" tab to publish specific posts for visitors
  - ☐ Twitter - tips for beginners https://medium.com/@buffer/twitter-tips-for-beginners-everything-i-wish-i-knew-about-twitter-when-i-started-a716e70276c
  - ☐ Press release about the launch of your DPC practice http://www.bizjournals.com/wichita/blog/2014/12/atlas-md-adding-second-wichita-location.html
  - ☐ Sample Press Release See attached files...
  - ☐ Meet with local SHRM - society of human resource management http://goo.gl/pGtbn2
  - ☐ Find retiring physicians See attached files...

- **9. Pricing Structure for Patients**
  - ☐ Age Based - Set ages
  - ☐ Not Age Based - set prices
  - ☐ Patient Enrollment form See attached files...
  - ☐ Release of Records See attached files...
  - ☐ Patient History Form See attached files...

- **10. Medications**
  - ☐ Set up andameds.com account See attached files...
  - ☐ Pill counter from rxcount.com
  - ☐ Order bottles/lids
  - ☐ Labels
  - ☐ Printers - Dymo See attached files...
  - ☐ Shipping Bags
  - ☐ Pharmacy bags - custom or generic
  - ☐ Inventory See attached files...
  - ☐ Script Paper See attached files...

- **11. Medical Supplies**
  - ☐ Andameds See attached files...
  - ☐ Other Reps
  - ☐ IRS Eligible Medical Expenses See attached files...
  - ☐ Cheap insulin/steroid inhalers See attached files...
  - ☐ Cheap othro glass https://goo.gl/omd5Q3

- **12. Labs**
  - ☐ Labcorp
  - ☐ Quest See attached files...
  - ☐ Local

- **13. Imaging and X-Rays**
  - ☐ Imaging Prices See attached files...
  - ☐ X-Ray Prices See attached files...

- **14. Radiology**
  - ☐ Use our prices to find local deals

- **15. Pathology**
  - ☐ Use our prices to find local deals

- **16. Staff**
  - ☐ No staff
  - ☐ Small Staff - RN or LPN or MA

- **17. Office Management**

- ☐ OSHA www.stericycle.com
- ☐ Hipaa www.stericycle.com
- ☐ Bio hazard waste removal www.stericycle.com
- ☐ Bookkeeper/HR/payroll - Quickbooks, freshbooks, Xero See attached files...
- ☐ Employee Benefits - medical, dental, vision, life, disability, retirement
- ☐ Credit Card Billing Auth See attached files...

- **18. Office Based Technology**

- ☐ Mobile - iOS or Android
- ☐ Office Computers See attached files...
- ☐ Printers for Office
- ☐ Printers for RX labels, lab labels, shipping
- ☐ Create RingCentral account for efax http://refer.ringcentral.com/USCA/accept-prospect/?EID=6e405a8f-dfea-4fd5-bf30-f91d69e94f71&type=ShareUrl
- ☐ Create Dropbox account > link to emr
  - DeleteEdit
  - ☐ Add digital signature to Adobe for easy electronic signing of documents

  Unassigned
- ☐ Phones - Standard line OR ringcentral OR grasshopper VOIP type
- ☐ Greeting cards - http://emilymcdowell.com

- **19. Master Checklist**
  - ☐ DPC Practice See attached files...

| Direct Patient Care Practice Checklist | | | | |
|---|---|---|---|---|
| **Waiting Room** | **Doctors Rooms** | **Pharmacy** | **Lab** | **Office** |
| Furniture | Exam Table | Pill Counter | Urinalysis Machine | Xerox Machine |
| Trash Can | Tissue Paper Rolls | Rx Bottles | Urine Dip Sticks | Dymo 4X6 |
| Music | Speculums | Dymo Printer | Autoclave | Dymo 4X6 |
| Coffee Machine | Chucks | 4X2 Dymo Labels | Autoclave Bags | Mail Scale |
| Coffee Cups | Furniture | Rx Cabinet | Bacterial Test Kit | Trashcan |
| Ipads | Cotton Balls | Poly Mailer Bags | Clia-Waived Tests | Phones |
| Art Work | Alcohol Pads | Drug Store Rx Bags | 1Cc Syringe | Interet |
| Blinds | Tongue Depressors | Www.Practrx.Com Account | 3Cc Syringe | Free Wifi |
| Sink | Ear Cannulas | Rx Basins | 10Cc Syringe | Secure Wifi |
| Trash Bags | Ky Lube | | 18 G Needle 1” | Money Box |
| Magazines | Kleenex | | 18 G Needle 1.5” | Secure Rx Paper |
| Kleenex | Paper Towels | | 22 G Needle 1.5 | Paper |
| Paper Towels | Sink | | 25 G Needle 1.5” | Stationary - Letter Head |
| Coffee Cup Sleeves | Clean Wipes | | 31 G Needle 1” | Stationary - Envelopes |
| Sweet & Low | Bandaids | | 4X4 Gauze | |
| Creamer | Otoscope | | Alcohol Pads | |
| Sugar | Opthalmoscope | | Iodine Pads | |
| Straws | Emesis Basins | | Trash | |
| Coffee Table | Trash | | Biohazard Trash | |
| | Biohazard Trash | | Sharps Container | |
| | Soap Dispenser | | Suture | |
| | Coat Rack | | Scapels | |
| | Art Work | | Ear Wash Kit | |
| | Iodine Pads | | Eye Wash Attachment For Facuet | |
| | Sharps Container | | Cleaning Supplies | |
| | Ekg Pads | | Surgical Tools | |
| | Gowns | | Electrocautery | |
| | Stethoscopes | | Microscope | |
| | Baby Plankets | | Glass Slides | |
| | Baby Scale | | Refrigerator | |
| | Head Circumference | | Refrigerator Thermometer | |
| | Eye Chart | | Refrigerator Thermometer | |
| | Scale | | Punch Biopsies | |
| | Height | | Lidocaine | |
| | Vitals Machine | | Lidocaine With Epi | |
| | Morgan Lens Kit | | Iv Fluid | |
| | | | Iv Supplies | |
| | | | Urine Containers | |
| | | | Emesis Basins | |
| | | | Spill Powder | |
| | | | Osha Labels | |
| | | | Msds Sheets | |
| | | | Woods Lamp | |
| | | | Protest Biological Test - Autoclave | |

| Direct Patient Care Practice Checklist | | | | |
|---|---|---|---|---|
| **Break Room** | **Procedures** | **Compliance** | **Dme** | **Business** |
| Osha Signs | Ekg | Osha | Crutches | Accountant |
| Refrigerator | Spirometry | Hipaa | Post Op Shoes | Payroll |
| Table | Urinalysis | Fire Plan | Cam Walkers | Hr |
| Chairs | Clia-Waived Tests | Fire Extinquishers | Cock Up Wrist Splints | Vacation Days |
| Cups | Cautery | Crash Cart | Rib Belt | Holidays |
| Plates | Ultrasound | Defibrilator | Knee Immobilizer | Rent |
| Silverware | Ultrasound Gel | Wheelchair | Shouler Slings | Utilities |
| Wire Shelves | | Policies & Procedures | Ace Wraps | Quaterly Taxes |
| | | Laundry Service | Kurlex | |
| | | Biohazard Service | Speculums | |
| | | | Speculum Lights | |
| | | | Biohazard Bags | |
| | | | Trash Bags | |

| Direct Patient Care Practice Clinical Forms | | | |
|---|---|---|---|
| Membership Forms | Marketing | Website | Clinical |
| Agreement | Flyers | Online Enrollment | Pdq-9 |
| CMS Waiver | Price List | Faq | Adhd Screen |
| HIPAA Waiver | Business Cards | Hours | Epworth Sleepiness Scale |
| Release Of Records | Letterhead | Price | |
| CC Billing Auth | Envelopes | Doctor Bio | |
| Pt Hx Form | | Directions | |
| | | Mobile Friendly | |

# IWantDirectCare survey

Direct Care is a retainer-based, insurance-free primary care model that's actually affordable and actually effective. Help us gauge the local demand for direct care by completing our survey.

PLEASE INDICATE IF YOU AGREE OR DISAGREE WITH THE FOLLOWING STATEMENTS

*[SD: strongly disagree, D: disagree, N: neutral, A: agree, SA]*

| | SD | D | N | A | SA |
|---|---|---|---|---|---|
| + I will ignore a pressing medical issue to save money. | ○ | ○ | ○ | ○ | ○ |
| + I will avoid follow-up visits with a physician to save money. | ○ | ○ | ○ | ○ | ○ |
| + I have had trouble scheduling an appointment with a provider when it was urgent. | ○ | ○ | ○ | ○ | ○ |
| + I am satisfied with my current healthcare plan. | ○ | ○ | ○ | ○ | ○ |
| + I understand what I am paying for when I receive a medical bill. | ○ | ○ | ○ | ○ | ○ |
| + I have experienced "sticker shock" after reviewing my medical bill. | ○ | ○ | ○ | ○ | ○ |
| + Last year, I clearly recall meeting my health insurance deductible. | ○ | ○ | ○ | ○ | ○ |
| + I understand my current health insurance plan (i.e. deductibles, copays, in-network vs. out-of-network costs, etc.) | ○ | ○ | ○ | ○ | ○ |
| + The media is fairly covering stories of cash-only doctors (Direct Care, Concierge Medicine, etc.) | ○ | ○ | ○ | ○ | ○ |
| + I would like to lower my monthly health insurance premium. | ○ | ○ | ○ | ○ | ○ |
| + I would pay upfront for unlimited, 24/7 access to a qualified physician with $0 copays. | ○ | ○ | ○ | ○ | ○ |
| + I would buy wholesale prescriptions out-of-pocket if the prices were lower than my copay. | ○ | ○ | ○ | ○ | ○ |
| + I would pay a yearly fee for access to a personal physician who would handle my non-life-threatening ER/Urgent Care needs. | ○ | ○ | ○ | ○ | ○ |
| + I would like it if a doctor could negotiate steep discounts on services like MRIs and CT-Scans. | ○ | ○ | ○ | ○ | ○ |
| + I want to know what I'm actually paying for when I receive a medical bill. | ○ | ○ | ○ | ○ | ○ |
| + I would gladly consult a doctor in lieu of scheduling a full appointment. | ○ | ○ | ○ | ○ | ○ |
| + I would like to text my family doctor if I have questions regarding a recent diagnosis and treatment. | ○ | ○ | ○ | ○ | ○ |
| + I am familiar with "wrap-around" insurance plans (also called "catastrophic care" plans) | ○ | ○ | ○ | ○ | ○ |
| + I understand the difference between concierge medicine and Direct Care. | ○ | ○ | ○ | ○ | ○ |
| + I am interested in learning more about the Direct Care model of primary care. | ○ | ○ | ○ | ○ | ○ |
| + I know how to find practitioners offering Direct Care services. | ○ | ○ | ○ | ○ | ○ |

THANKS FOR COMPLETING THE SURVEY!

By cutting out the insurance middleman, doctors can skip the bureaucracy and spend time caring for patients. And patients can lower their overall medical expenses by paying only for what they need. However, it'll take ingenious doctors and smart patients to turn common sense into the status quo for primary care.

SELF EVALUATION

**Direct Patient Care: Understanding the Model**

**True/False**

**1.** Direct primary care is the same as concierge medicine.

**2.** DPC could make the shortage of physician worse.

**3.** Physicians in this model make less money than physicians who accept insurance.

**4.** There is only one correct way to do DPC.

**5.** Specialists can do an outpatient insurance free model too.

**6.** You can't be a good business person and a caring physician.

**7.** It takes a lot of financial resources to start a DPC practice.

**Answer Key:** 1. F, 2. F, 3. F, 4. F, 5. T, 6. F, 7. F

## Jeffrey O. Capes, DMD, MD

Jeffrey O. Capes, DMD, MD, of St. Simons Island, GA, is an oral and maxillofacial surgeon who holds doctorate degrees in both dentistry and medicine and is licensed to practice both. He heads Coastal Oral Surgery, is a frequent speaker, a diplomate of the American Board of Oral Implantology, and a fellow of the American Association of Oral and Maxillofacial Surgeons.

You may contact Dr. Capes at (912) 634-6600, or by email at jeff@capesoralsurgery.com.

Jeffrey O. Capes
D.M.D, M.D.
*Diplomatic American Board of Oral Implantology*
*Assoc. Fellow American Academy of Implant Dentistry*



## Odontogenic Infections - Part 1: Diagnosis and Surgical Treatment Options

### A Thought

To Make Wise Decisions In Any Arena Requires An Understanding Of and Submission to The Principles And Rules That Govern That Arena.

Principles and Rules Inform the Decision Process.
They Create the Context for Good Judgement.

### Odontogenic Infections

- Important for MD and DMD
- Patients will present to both
- One most commons reasons to visit ER/Urgent Care
- Recognition and proper management
- Avoid Severe Complications
- Avoid Admission to Hospital

### Odontogenic Infections

- Presentation
- Cause
- Stages
- Microbiology
- Treatment
- Surgery
- Antibiotics

### Presentation

- Differential
- Stages
- Initial/early
- Onset
- Established
- Severe

### Differential

- Reactive
- Angioedema, Drug Allergy
- Sinus
- Salivary Glands
- Tumor
- Odontogenic

### Presentation

- Pain
- Loss of Function
- Swelling
- Systemic fever/malaise
- Clinician
- History/ROS
- Medically Compromised

110 Office Park Lane • Suite 104 • St. Simmons Island • Georgia 31522
phone 912.634.6600 • fax 912.634.3882

## Cellulitis vs Abscess

- Important to Differentiate
- Behave differently

## Cellulitis

- Duration
- Pain
- Size
- Localization
- Palpation
- Pus
- How Serious
- Bacteria

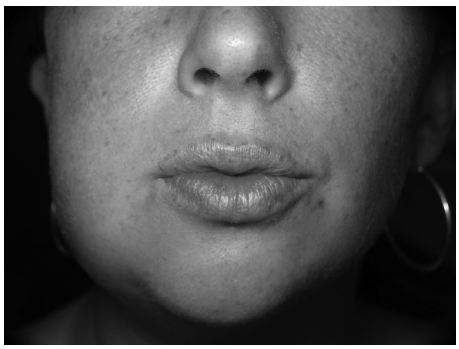
- Acute
- Severe / generalized
- Large
- Diffuse Boarders
- Doughy/Indurated
- No
- Greater
- Aerobic

## Abscess

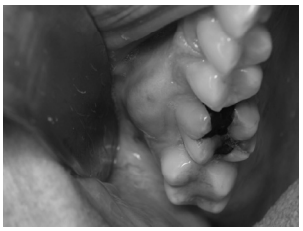
- Duration
- Pain
- Size
- Localization
- Palpation
- Pus
- How Serious
- Bacteria

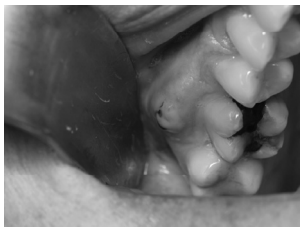
- Chronic
- Localized
- Small
- Well Circumscribed
- Fluctuant
- Yes
- Less
- Anaerobic

## Cellulitis



## Abscess





## Physical Exam

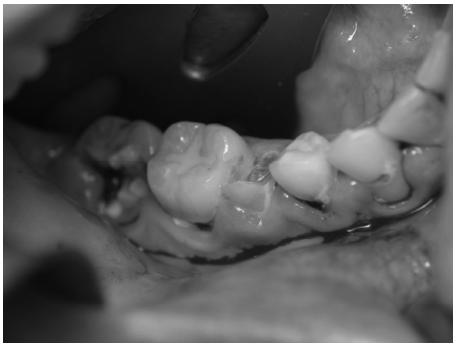
- Establish the Etiology
- Anatomic sites
- Neurologic status
- Respiratory patterns
- Potential of Spread

## Causes of Odontogenic Infection

- Poor Oral Hygiene
- Dental Neglect
- Periodontal (Gum) Issues/Disease
- Tooth Decay/Breakdown
- Most Common source is the dental pulp
- Trauma/Surgery

## Findings Odontogenic

- Carious Lesions
- Parulis
- Swelling adjacent to teeth
- Thermal Response changes
- Sinus/Fistula tracts
- Percussion tenderness
- Pus



## Cardinal Signs

- Rubor=Redness
- Tumor=Swelling
- Calor=Warmth
- Dolor=Pain

## Systemic

- Fever
- Tachycardia
- Increased Respirations

## Trismus

- Limited ROM
- Infection spread to Muscles of Mastication

## Spaces and Presentation

- Buccal/Vestibule
- Masticatory
- Canine
- Submandibular
- Submental/FOM
- Temporal
- Lateral Pharyngeal
- Peritonsillar
- Retropharyngeal /Danger Space

## Deep Space Involvement

- Trismus
- Dysphagia
- Swelling
- Displacement of the Uvula
- Angle of the Mandible forward to the SubMental Area

## Deep Space Infections

- Airway

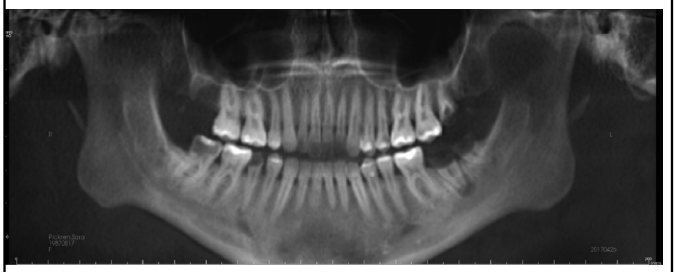
## Indications for Referral

- Rapidly Progressing
- Difficulty Breathing
- Difficulty Swallowing
- Fascial Space Involvement
- Elevated Temperature
- Toxic Appearance
- Compromised Host Defenses

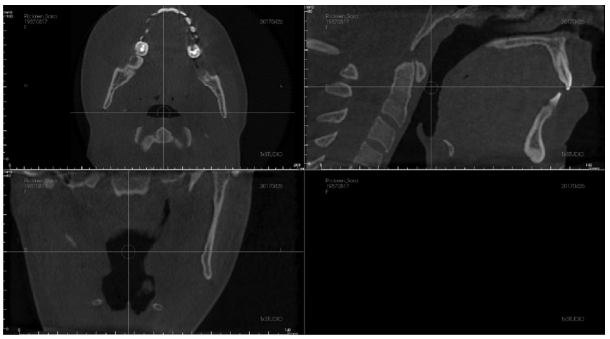
## Lab/Radiographic Evaluation

- CBC w/ diff
- Panorex
- CT Scan

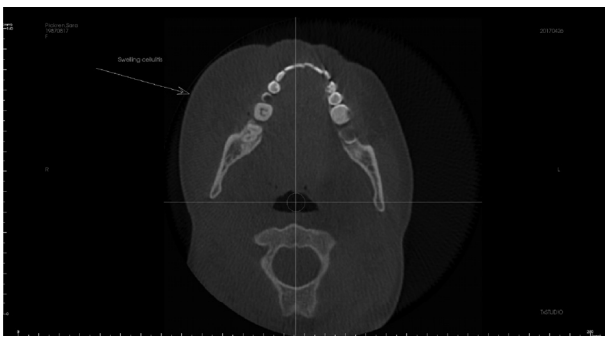
## Panorex



## CT image



## Swelling Cellulitis




## Treatment / Surgery

- Antibiotic
- Surgery

- First line identify and remove the source
- Incision and Drainage
- ? Penrose Drain
- Monitor Patient
- Re-evaluate Frequently
- Response

## Microbiology

- What are the Bugs?
- What Antibiotic?
- To Culture or Not to Culture
- Aerobic
- Anaerobic
- Mixed

## Culture and Sensitivity

- Rapidly Spreading Infection
- Post-Op Infection
- Non-Responsive infection
- Recurrent Infection
- Compromised Host Defenses

## Microbiologic Considerations

- Identify The Bacteria
- Obtain a Good Specimen
- Aspiration vs swab
- Gram Stain

## Most Common Bacteria Isolated

**Aerobic**

- Streptococcus Viridans
  - Mitis
  - Anginosus
  - Mutans
  - Salivarius
  - Bovis

**Anaerobic**

- Peptostreptococcus
- Fusobacterium
- Bacteroides
- Provotella

## Conclusion Part 1

- Presentation
- Determine Stage/Severity
- Findings
- Assess Danger Signs
- Determine Treatment
- Microbiology

## Principles of Management of Odontogenic Infections

- Determine Severity
- Evaluate Host Defenses
- Determine the Setting of Care
- Support Medically
- Treat Surgically
- Choose and Prescribe Appropriate Antibiotics
- Administer Antibiotic Appropriately
- Evaluate Frequently

SELF EVALUATION

**Odontogenic Infections - Part 1: Diagnosis and Surgical Treatment Options**

**True/False**

**1.** 2-3% of all visits to the ER/Urgent care are related to odontogenic pain or infection.

**2.** It is important to distinguish cellulitis from abscess because they behave differently.

**3.** Cellulitis presents acutely with diffuse swelling and severe pain.

**4.** Abscess presents with longer duration, small localized swelling that tends to be fluctuant.

**5.** The most common source of odontogenic infection is the dental pulp.

**6.** Systemic responses to odontogenic infections include tachycardia, fever, and increased respirations.

**7.** Trismus is a term to mean limited range of motion.

**8.** Danger signs which indicate referral include rapidly spreading, difficulty swallowing, deep space involvement, and compromised host defenses.

**Answer Key:** 1. T, 2. T, 3. T, 4. T, 5. T, 6. T, 7. T, 8. T

## Rebecca Jaffe, MD, MPH, FAAFP, FACSM

Rebecca Jaffe, MD, MPH, FAAFP, FACSM, of Wilmington, Delaware, heads a private practice specializing in family and sports medicine and maintains her family medicine board certification. She served on the boards of directors for the AAFP, the AAFP Foundation and Christiana Care Health System, and is a past chair of the AAFP's Women's Health Conference CME. Dr. Jaffe is a past president of Delaware Academy of Family Physicians and is an instructor in Jefferson Medical College's Department of Family Medicine. She has authored numerous professional publications and is a frequent speaker to regional, national and international conferences.

You may contact Dr. Jaffe with your questions or comments at 302-540-1665, or by email at RJHDocMom4@gmail.com.

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**Recognizing and Responding to Child Abuse**

## Child abuse- Learning objectives

- Participant will be able to :
  - 1. Identify major types of child abuse.
  - 2. Will be able to recognize consequences of exposure to child abuse
  - 3. Will understand prevention strategies to better support a healthy child environment.

## Child abuse

- **Third leading cause of death in children between 1 & 4 years of age**
- **Almost 20% of child homicide victims have contact with a health care professional within a month of their death**.

## In the news

- Delaware: *Former pediatrician Earl Bradley was found guilty of raping or abusing patients in 2011.*
- *Illinois:* Dennis Hastert: Child Molester
- *"Church"*
- *"Penn State" scandal*


## Federal Child Abuse Prevention and Treatment Act 1974

- Amended by the Keeping Children and Families Safe Act of 2003
- Defines abuse as **"any recent act or failure to act on the part of a parent or caretaker which results in death, serious physical or emotional harm, sexual abuse or exploitation" or " an act or failure to act which present an imminent risk of serious harm"**

## Federal Child Abuse Prevention and Treatment Act 1974

- Amended & reauthorized 12/20/10
- CAPTA reauthorization Act of 2010
  - Supports
    Prevention, assessment, investigation, prosecution and treatment activities

## LEGAL OBLIGATION TO REPORT IN ALL 50 STATES AND DC

## Child abuse in US:

- More than 10 million children younger than 18 years experience some from of maltreatment from a caregiver, ranging from neglect to sexual abuse, but only a small % of these violent incidents are reported to law enforcement, health care clinicians or child protective agencies.

## Child Abuse

- Meta-analysis- **exposure to physical abuse in childhood is associated with 54% increased odds of depressive disorder, 78% increased odds of STI or risky sexual behavior and 32% increased odds of obesity.**

## CHILD ABUSE

- ***EXPOSURE TO VIOLENCE AS A CHILD (EITHER DIRECTLY OR AS A WITNESS) IS A STRONG AND CONSISTENT PREDICTOR OF FUTURE VIOLENCE EXPOSURE AS WELL AS THE PERPETRATION OF VIOLENCE AS AN ADOLESCENT OR ADULT.***

## HIGH RISK 4 abuse

- Child with disabilities
- Household with unrelated adults
- Maternal smoker
- Single mother
- Presence of 2 or more sibs

- **Child- individual under 18**
- **Perpetrator- does something to harm or cause potential harm to a child**
  - **Committing an act**
  - **Failing to act**

## Specific Acts of Child Abuse

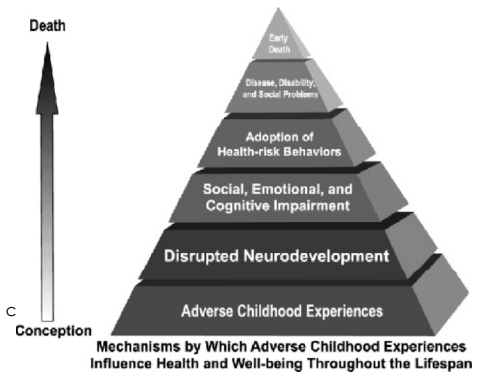
- Bodily injury (physical)
- Serious mental injury
- Serious physical neglect
- Sexual abuse or exploitation
- Sexual misconduct

## NEGLECT

- ALMOST 80%
- FAILURE TO MEET BASIC NUTRITIONAL, MEDICAL, EDUCATION AND EMOTIONAL NEEDS OF A CHILD

## CHILD FATALITIES

- 2013
- **NATIONALLY 1520 CHILDREN DIED**
  - **¾ WERE LESS THAN 3 YEARS OLD**
  - **4/5 WERE CASED BY 1 OR BOTH PARENTS**



Mechanisms by Which Adverse Childhood Experiences Influence Health and Well-being Throughout the Lifespan

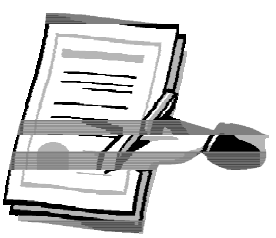
## Heightened Index of Suspicion

- The injuries
- "those who don't cruise, don't bruise
- Burns
- Fractures in unlikely places
- Bruises

## TEN-4 rule

- **Bruising on the torso, ear or neck (TEN) in a child 4 yrs or younger or bruising of any region in a child younger than 4 months, requires further evaluation for abuse.**
- Sensitivity 97%, specificity 84%

## DOCUMENTATION



## Communication

- Rapport
- Neutral
- Privacy
- Duty
- Available

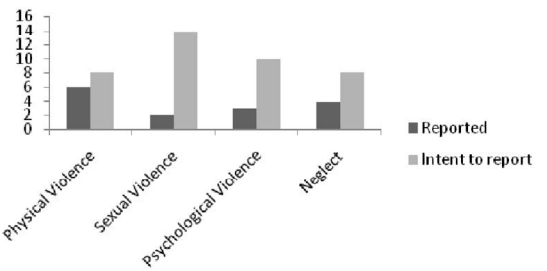
## Survivors of abuse

- Depression
- Conduct disorders
- Drug abuse
- Cigarette smoking
- PTSD

- **Scientific literature clear—**
  - **Prevention**
    - **Children and youth**
      - **Education, behavior change, policy, environmental and social support**

- **Vital that public health and clinical medicine intersect**
- **and work together**

## PROTECTION/REPORTING

## resources

- Childhelp National Child Abuse Hotline
- 800-4-A-ChiLD (800-422-4453)

- REPORTING: CHILDLINE- 1800 932 0313

## ADDITIONAL RESOURCES

- Prevent Child Abuse America. Preventing Child Neglect. www.preventchildabuse.org
- Child Welfare Information Gateway. www.childwelfare.gov
- US Dpt of Health and Human Services. Admin for Children and Families www.acf.hhs.gov/programs/ch/research-data-technology/statistics-research/child-maltreatment

SELF EVALUATION

**Recognizing and Responding to Child Abuse**

**True/False**

**1.** Child abuse statistics are valid and verified.

**2.** As a health professional, you have a legal obligation to report child abuse in the United States.

**3.** When you learn that someone is a victim of child abuse, you isolate them from their family

**4.** If someone claims to have been sexually assaulted, you bring them to an emergency room for further evaluation.

**5.** Most child abuse occurs in the first 6 months of life.

**6.** Child Abuse is unique to the Western Hemisphere

**7.** Most cases of child abuse are sexual.

**8.** There are many health consequences to individuals who suffer from child violence.

**Answer Key:** 1. F, 2. T, 3. F, 4. T, 5. F, 6. F, 7. F, 8. T

woodcock & associates
CHANGING THE WAY YOU WORK

**Effective Revenue Cycle Management - Part 2: After the Encounter**
***Elizabeth W. Woodcock, MBA, FACMPE, CPC***

## Agenda

- Charge Capture and Finalization
- Insurance Follow-up
- Account Audit
- Payment Monitoring
- Bad Debt Avoidance
- Performance Monitoring





## Charge Capture and Finalization


**24 to 72 hours**



## Charge Capture and Finalization

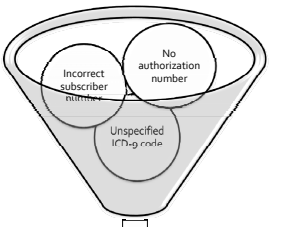
- Charge reconciliation protocol
  - Office visits
  - "Other" services in the office
  - Hospital visits, consults and surgeries/procedures
  - Other places of service





## Insurance Follow-up

Garbage In…




…Garbage Out!

**Insurance Follow-up**



## Insurance Follow-up

**Still in your Hands**

**[Charge Edits, Clearinghouse Edits, Errors, Rejections]**

**The Payer's Claims Adjudication System**




## Insurance Follow-up

- Pay Correctly
- Pay Incorrectly (Underprofile)
- Deny
- No Communication

## Insurance Follow-up


**Claim Adjustment Reason Code**

PR 1 - Deductible Amount → "Soft" Denial

CO 15 - The authorization number is missing, invalid, or does not apply to the billed services or provider. → "Hard" Denial

http://www.wpc-edi.com/reference/



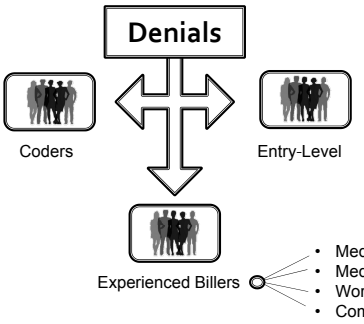
## Insurance Follow-up



**Go Team!**



## Insurance Follow-Up




- Medicare
- Medicaid
- Workers' Comp
- Commercial



## Insurance Follow-up

**Build Workqueues…**

1. **Timely filing deadlines**
2. **Dollars**

- **Sort by Payer**
- **Sort by Service (CPT)**



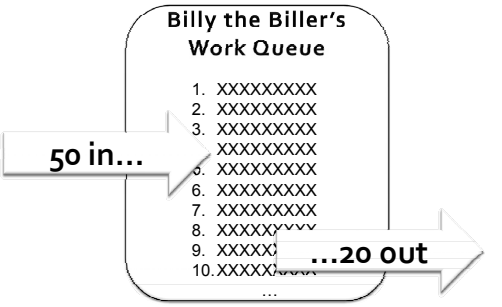

## Insurance Follow-up

**Follow *payers'* payment cycles to work insurance receivables**

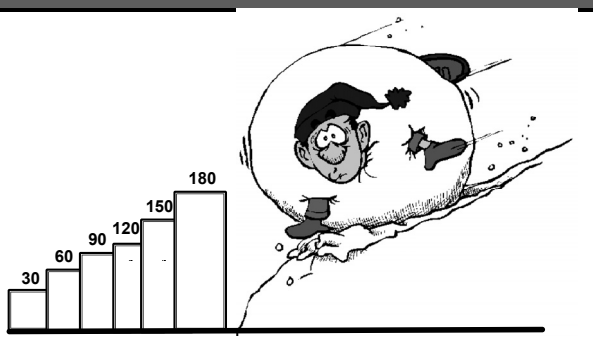
*The time between the practice submitting the claim – and the payer remitting payment.*




## Insurance Follow-up

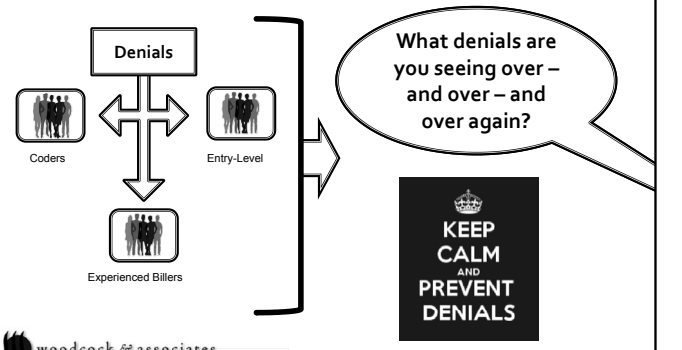


## Insurance Follow-up






## Insurance Follow-up






## Account Audit

Audit

1. Choose a single date of service ~nine months ago
2. Query for all open invoices
3. Randomly choose 50+/- of them
4. Pull all activities and notes associated with the invoices
5. Evaluate

**Terrific approach to employees' performance evaluations!**





## Account Audit

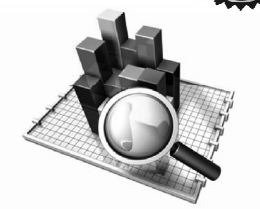
Remember, this is a biased sample…

- Who was responsible for non-payment?
- Were appropriate and timely actions taken?
- Were appropriate adjustments taken?
- Is the invoice in the hands of the correct financially responsible party now?
- Did the notes explain the employee's actions? Can you understand them?





## Account Audit

)0% Adjustment Report

[line item level]

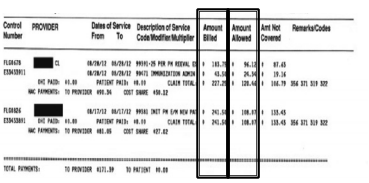




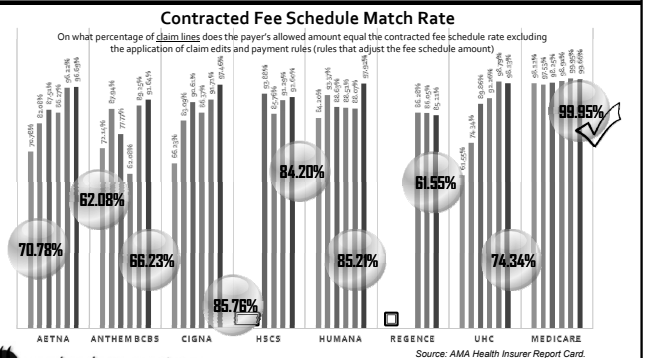
## Payment Monitoring


- Identify Underprofile Payments
  - Load current allowables for all payers/products
  - Review at the line item level
  - Take action

1 Line item 2 Bulk



## Payment Monitoring






## Bad Debt Avoidance


1. Automate the "flip" to patient accountability… and the entire dunning process
2. Transmit statements regularly
3. Follow your own protocols for managing collections




## Bad Debt Avoidance

- Review language and structure

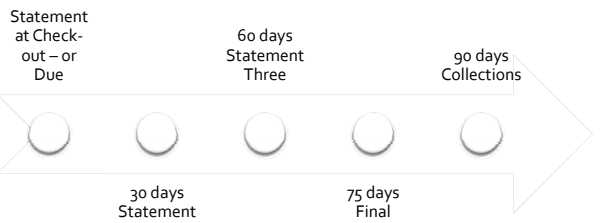
| Current | 31 to 60 | 61 to 90 | 91 to 120 | Over 120 |
|---|---|---|---|---|
| | $100 | | | |

**Place an actual due date on statements (and letters)**

**Maintain an open balance for the business office manager; send to his/her address**



## Bad Debt Avoidance




***Send twice-monthly statements***



## Bad Debt Avoidance



Dear Patient:
In an effort to be more environmentally friendly, Rheumatology Practice Associates now offers eStatements. Choosing this option allows you to receive your statements electronically, sent to you via email. You no longer have to hassle with paper statements. In addition to being environmentally friendly, eStatements are convenient and secure. As soon as your statement is ready, you will be notified via email. The email will provide a link to a secure website where you can not only view your statement, but also choose one of several payment options.

Don't want to go paperless? Not a problem. If you would like to continue to receive paper statements in the mail, you'll be required to pay an annual fee of $20 which is due today. Please let us know!

- ❑ Yes, I want the environmentally friendly option; instead of paper, please send my statements to: _____ .
- ❑ No, I would like to continue receiving paper statements, and will pay the annual fee of $20.

_____
Guarantor Signature/Name/Date

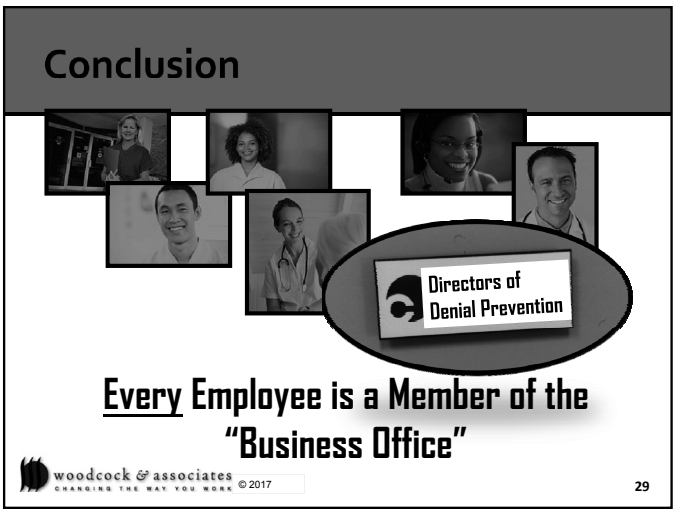


## Performance Monitoring

| Key Performance Indicator | *The Practice* | *High Performers* | *Expected Range* |
|---|---|---|---|
| Days in Receivables Outstanding | | 30.06 | 30 to 40 |
| Percent of Receivables Over 120 Days | | 12.57% | 10 to 15% |
| Adjusted Collection Rate | | 100.00% | 96 to 98% |
| Cash | | $? | $? |

*Source for "High Performers": MGMA 2016 Cost and Revenue Report, 75%ile data for multispecialty, all practices.*

IMPACT **Payer Mix**




SELF EVALUATION

**Effective Revenue Cycle Management - Part 2: After the Encounter**

**1.** T/F - Insurance companies pay *every* claim correctly upon initial submission.

**2.** The names of the "codes" that will indicate the reason for the denial are called:
- a. Insurance naming codes
- b. Error codes
- c. Claim adjustment reason codes
- d. Payment rejection codes

**3.** The key to successfully capturing charges outside of the office is to create a systematic approach that:
- a. Requires an employee to serve as a runner to the hospital
- b. Ignores services that were performed by advanced practice providers
- c. Offers the ability to be reconciled with a source document such as the OR log
- d. Provides a variety of bright colored index cards to retain information

**4.** It is much better to "clean" a charge by working a claim edit _____ the charge is released from your system and the payer adjudicates the claim.
- a. After
- b. Between the time that
- c. Before
- d. All of the above

**5.** Load expected payer reimbursement schedules into your practice management software so that remittances with _____ below expected values can be identified at the transaction level; these exceptions can be identified and documented on a report or loaded into a work file for an employee to take further action.
- a. Employees
- b. Payments
- c. Small claims court cases
- d. Bank routing

**6.** Make every effort to ensure that claims are _____ so that they aren't denied.
- a. Clean
- b. Assembled
- c. Lost
- d. Transmitted

**7.** Prioritize accounts receivable requiring more "follow-up" work based on:
- a. Payers' timeframes for filing and dollars outstanding
- b. Greatest number of CPT® and ICD-10 codes
- c. Most available provider representatives
- d. Highest volume of claims and lowest hold time on customer service line

**8.** Evaluate the number of accounts that your employees have the capacity to work, compared to the number of accounts that require work; if these are not equal, a(n) _____ effect will result and problems will ensue.
- a. Rainbow
- b. Snowball
- c. Peaceful
- d. Incentive

**9.** The 100% _____ report allows you to monitor whether services are being inappropriately written off.
- a. Adjustment
- b. Audit
- c. Biller motivation
- d. Transaction remittance

**10.** The following are key performance indicators or the revenue cycle:
- a. Days in receivables outstanding
- b. Percent of receivables over 120 days
- c. Adjusted collection rate
- d. Cash
- e. None of the above
- f. All of the above

**11.** T/F - Every employee in your practice is a member of the billing office.

**12.** Sending _____ statements allows you to communicate more with your patients, during the same period of time. Further, this technique allows you to time your statements with your patients' _____ cycle.
- a. Pretty; shift
- b. Bimonthly; payroll
- c. Paper; electronic
- d. Multiple; mail

**Answer Key:** 1. F, 2. C, 3. C, 4. C, 5. B, 6. A, 7. A, 8. B, 9. A, 10. F, 11. T, 12. B

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# Odontogenic Infections - Part 2: Antibiotic Therapy

## Antibiotic

- ? Necessary?
- Indications
- Acute onset
- Diffuse Swelling
- Compromised Host
- Spreading to fascial Spaces

## Principles of Antibiotic Therapy

- Remove Cause and Establish Drainage Primary
- Specific Antibiotic Therapy
- Narrowest Spectrum Drug
- Base on C and S
- Low Toxicity
- Bactericidal
- Duration
- Cost should be aware

## Principles of Antibiotic Therapy

- Proper Dose and Frequency
- Proper Route
- Our Responsibility
- Adequate Duration
- Educate the Patient

## Drug Compliance

- Dosage interval encourages compliance
  - QD or BID = 70%
  - QID = 40%
- Non-compliant after starting feeling better
  - 3-5 days = 50%
  - >7 days = 20%

## Antibiotic Review

- Antibiotic
- Any semisynthetic, or totally synthetic antimicrobial agent that inhibits bacterial growth
- Two Classifications
- Bacteriocidal
- Bacteriostatic

## Bacteriocidal

- Directly kill infecting organism
- Best for Immunocompromised Patients

## Bacteriostatic Drugs

- Inhibit Proliferation of bacteria by interfering with an essential metabolic process
- Host Immune system Ultimately Eliminates Bacteria
- Equally effective In Immune Competent Patients as Bacteriocidal Drugs

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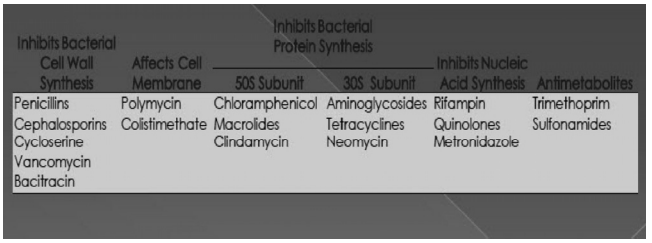
## Sites and MOA Of Antibacterial Agents

Table 9-1 Sites and Mechanisms of Action of Selected Antibacterial Agents

| Inhibitors of Cell Wall Synthesis | Inhibitors of Protein Synthesis (Translation) | Inhibitors of DNA Synthesis and Integrity |
|---|---|---|
| Penicillins | Macrolides | Metronidazole |
| Cephalosporins | Clindamycin | Fluoroquinolones |
| Bacitracin<br>Vancomycin | Tetracycline (doxycycline, minocycline)<br>Neomycin | |

## Antimicrobial Mechanisms and Sites




## Antibiotic Choice

- The Right Drug for The Right Bug
- Lack of Information
- C and S take time

## MOA

- Bactericidal Drugs
- Target Metabolic Pathways for Survival
- Bacteriostatic Drugs
- Target Metabolic Pathways necessary for Growth

## Pen VK

- Louis Pasteur 1877
- Alexander Fleming 1928
  - As Dr. Fleming famously wrote about that red-letter date: "When I woke up just after dawn on September 28, 1928, I certainly didn't plan to revolutionize all medicine by discovering the world's first antibiotic, or bacteria killer. But I guess that was exactly what I did.
- The "aspirin" of oral infections
- Good Spectrum
- Best Bang for the Buck (free)

## Penicillins

- Pen VK
- Bactericidal
- Tabs 250 mg, 500 mg
- Susp 125mg/5ml; 250 mg/5ml
- Minimal toxicity
- N,V,GI distress, diarrhea, hypersensitivity rxn, fungal overgrowth, anaphylaxis
- Cat B

## Penicillin Hypersensitivity

- On hypersensitivity reaction the data states between .7% upto 10% risk of hypersensitivity reaction
- Anaphylaxis(1-5 per 10000)
- True drug allergy is rare
- Acute vs Sub-acute
- IgE mediated vs IgG mediated
- Higher with parental administration vs oral route

## Penicillin Hypersensitivity

**ACUTE**

- Immediate/rapidly
- Sudden Anaphylaxis
- Hypotension
- Bronchospasm
- Angioedema
- Urticaria/Hives
- Ig-E due to previous exposure
- Mast cell-histamine

**SUB-ACUTE**

- 7-10 days
- 1-2 days after repeat tx
- Urticaria/Hives
- Fever
- Arthralgias
- Ig-G mediated due to previous treatment
- Activation of Complement reactions = inflammation

## Penicillin Skin Testing

- Why perform?
- Prick test/Intradermal test
- Qualm fears
- Confirm safety of using the drug
- + = presence of IgE antibodies
- - = no greater risk of rashes to penicillin are consider to have risk as general population
- Benefit

## Penicillin Allergy

- Mild hypersensitivity
- Diphenhydramine
- Anaphylaxis = medical emergency
- Epi/Corticosteroids

## Pen Cross Sensitivity

- Immediate Type Hypersensitivity should NOT be given any other penicillin drug
- Past estimated 10% with Cephalosporins
- Due sharing B-lactam ring
- Recent data reaction = side chain of the 1st generation cephalosporins and Pen
- Means the risk may be low to non existant as long as the side chains are not similar

## Cross Reaction Cephalosporins

**HIGH LIKELY**

- Cephalexin
- Cefadroxil
- Ceflaclor
- Cephradine
- Cefprozil
- Ceftriaxone
- Cefpodoxime

**SAFER LACK B-LACTAM SIDE CHAIN**

- Cefazolin
- Cefuroxime
- Cefdinir
- Cefixime
- Ceftibuten

## Conclusion Penicillin

- With reported "allergy"
- 90% are not truly allergic
- Careful with our words allergy vs hypersensitivity
- 10% cross reactivity with Cephalosporins is probably too high (mostly associated 1st generation)

## Pen VK Dosing

- Loading 1-2 gm
- 250-500 QID 5-10 days
- Child 125-250mg QID

## Amoxicillin

- Batericidal
- Caps 250, 500 mg
- Tabs 500, 875 mg
- Chewable 200, 400 mg
- Susp 50mg/ml, 125mg/5ml, 200mg/5ml, 250mg/5ml, 400mg/5ml
- N, V, diarrhea, colitis, hypersensitivity, blood dyscrasias
- Cat B

## Amoxicillin

- Loading Dose 1-2 gm
- 250-500 TID 7 days
- 875 mg BID
- Child based on weight

## Amoxicillin Clavulanate

- Bactericidal
- Tabs 250/125 mg, 500/125 mg, 875/125 mg
- Chewable 125/31.25 mg, 200/28.5 mg, 250/62.5 mg, 400/57 mg
- Adverse rxn same as Amoxicillin plus urticarial, vaginitis
- Dosing based on Amoxicillin
- TID or BID
- Cat B

## Cephalosporins

- Cephalexin (Keflex) 1st Generation
- Bactericidal
- Caps 250, 500 mg
- Susp 125mg/5ml; 250mg/5ml
- 1st Generation
- Similar side effects to Pen VK
- Loading 1-2 gm
- 250-500 mg QID
- Cat B

## Cephalosporins

- Cefadroxil (Duricef) 1 st Generation
- Caps 500 mg
- Susp 250mg/5ml; 500mg/5ml
- 1st Generation
- Similar side Effects
- Dosing 500 mg BID
- Cat B

## Cephalosporins

- 2nd Generation
- Cefaclor (Ceclor), Cefprozil (Cefzil), Cefuroxime (Ceftin)
- Similar dosing and side effects

## Clindamycin

- Bactericidal/Static
- 150mg, 300mg
- Loading Dose 600mg
- 300 mg TID
- 7 day course
- GI, N, V, Clostridium difficile colitis, Psuedomembraneous Colitis

## Macrolides

- Azithromycin (Z-Pack)
- Bactericidal/static
- 250 mg packs 6 tabs 5 day course
- 500 mg tabs 3 tabs 3 day course
- Drug Interactions
- GI, N, V,
- Cat B

## Macrolides

- Clarithomycin ( Biaxcin)
- Tabs 250 mg, 500 mg
- Susp 125 mg/5ml, 250 mg/5ml
- Dosing 250-500 mg BID
- XL 1000 mg QD
- Drug interactions, GI, dysgeusia
- Cat C

## Macrolides

- Erythromycin
- Delayed Release caps 250 mg
- Tabs 250mg, 500mg
- Susp 100mg/5ml, 400mg/5ml
- Chew 200 mg
- Dosing 250 mg QID, 500 mg BID-QID
- Colitis, N, V, Abdominal pain, hepatic dysfunction
- Cat B

## Nitroimadazoles

- Metronidazole (Flagyl)
- Bactericidal
- Tabs 250mg, 500mg
- Dose 250-500mg TID
- Seizures, peripheral neuropathy, N, V, HA, Rash, dysuria, metallic taste, dizziness, vaginitis
- Cat B except 1st trimester
- ER 750 mg QD

## Antibiotic Associated Colitis

- C. Difficile colitis
- All antibiotics can be associated
- Est 500,000 cases per year

## Antibiotic Classes Highest Risk

- Ratio 5 or more
- Clindamycin 17-20 odds ratio
- Fluoroquinolones, Cephalosporins odds ratio 5

## Antibiotics Classes Moderate Risk

- Macrolides, Penicillins 1.8-3.3 odds ratio
- Pen > than Macrolides

## Risk Factors Colitis

- Age > 65
- Prolonged Therapy
- Multiple Antibiotic regimes
- Gastric Acid suppression
- GI surgery history
- Hospitalized Patient
- Female
- IBD
- Chemotherapy
- Renal Disease

## Antibiotic Associated Colitis

- 5 or more bloody/mucoid stools/day
- Abdominal Cramping
- Fever
- Lab C. difficile exotoxin stool sample
- Colonoscopy = sloughing mucosa
- 3 consecutive negative assays = neg result
- Treatment
- Metronidazole
- Oral Vancomycin
- 7-10 day course

## Summary on Antibiotics

- Pen VK and Amoxicillin
- Metronidazole
- Clindamycin
- 2-3 Days no improvement
- Change/B-Lactamase stable
- Amoxicillin Clavulanate
- Erythromycin
- 1st/2nd Generation Cephalosporins are effective
- Quinolones

## Current Thought on Infections

- Traditional views
- Science
- Studies

## Maxillofacial infections

- Organisms found info is scant and conflicting
- Success of treatment
- Recent studies suggest we treat with our traditional views
- New culturing techniques brought the role of anaerobic bacteria to forefront

## Patients and Methods

- 88 patients
- Pus obtained aspiration technique
- Gram stain performed
- Aerobic Processing
- Anaerobic Processing
- Culture and Sensitivity completed

## Results

- Buccal space infection most prevalent
- Mandibular Molars most common
- Over 50% presented on the 3rd-4th day
- Pus acquired 48 % 0-1 ml 45% 2-3 ml
- Only 12% foul smelling
- 92% green-yellow pus

## Microbiological Evaluation

- 68.2% Aerobic infections
- 9.1% Anaerobic infections
- 13.6% Mixed Infections
- 9% No growth

## Aerobic Infections

- 80% gram + cocci
- 19% gram – bacillius
- 1% gram + bacillus

## Anaerobic Infections

- 78.3% gram + cocci
- 21.7% gram - bacilli

## Organisms Isolated

**AEROBIC**

- Streptococcus sanguis 22%
- Streptococcus mitis 18%
- Enterococcus faecalis 12%
- B-hemolytic strep 10%

**ANAEROBIC**

- Peptostreptoccocus 70%
- Propionibacterium 17%
- Bacteroides
- Peptococcus
- Actinomyces

## Antibiotic Sensitivity

**PENICILLIN**

- 81.3 % were sensitive
- 18.8% resistant
  - Coag – Staph
  - Staph aureus

**CLINDAMYCIN**

- 93.6% were sensitive
- 4.3% resistant
- 2.1% intermediate sensitivity

**CIPROFLOXIN**

- 81.4 % sensitive
- 8.4% resistant
- 3.8% intermediate sensitivity

**CEFOTAXIME**

- 92% sensitive
- 6.6% resistance
- 1.6% intermediate sensitivity

## Results

- Aspiration Samples
- Infections are aerobic in nature
- Aerobic 68.2 vs Anaerobic 9.1%
- Mixed 13.6%
- With new state of the art isolation techniques
- Predominant Organisms are Aerobic
- No major change in microflora
- Streptococcus = aerobic
- Peptostreptococcus = anaerobic
- Most are Penicillin sensitive

## Take Home Message

- No change in the microflora causing infections
- Penicillin type antibiotics remain the drug of choice for treating these infections

## Treatment Summary

- Determine the Severity
- Complete History and Physical
- State of Host Defenses
- Treat the Infection Surgically
- Support the Patient Medically
- Choose Right Antibiotic
- Re-Evaluate Frequently
- Referral Specialist

SELF EVALUATION

**Odontogenic Infections - Part 2: Antibiotic Therapy**

**True/False**

**1.** First line of treatment of odontogenic infections is identifying the source and removal and incision and drainage when necessary.

**2.** Most common bacteria causing odontogenic infections are aerobic Streptococcus and anaerobic Pepto streptococcus.

**3.** Antibiotics are an adjunct therapy for removing the source and I and D of odontogenic infections.

**4.** Drug compliance is affected by dosage interval.

**5.** Antibiotics can be classified as either bacteriostatic or bacteriocidal.

**6.** The problem with choosing antibiotics based on culture and sensitivity is that it takes time.

**7.** Penicillin hypersensitivity and allergic anaphylaxis are mediated by two different immunoglobulins.
Hypersensitivity by IgG delayed
Allergic by IgE immediate

**8.** By adding clavulanate to amoxicillin it creates beta lactamase inhibition.

**9.** Antibiotic associated colitis is produced by Clostridium difficile and can be associated with any antibiotic.

**10.** Recent studies have shown the vast majority of odontogenic infections are aerobic in nature.

**11.** Recent studies have shown the predominant bacteria in odontogenic infections are Streptococcus and Pepto streptococcus and are still highly sensitive to penicillin and clindamycin.

**Answer Key:** 1. T, 2. T, 3. T, 4. T, 5. T, 6. T, 7. T, 8. T, 9. T, 10. T, 11. T

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# Managing Type 2 Diabetes in Older Adults

## Disclosures

Louis Kuritzky has been an advisor, consultant, or speaker for

Amgen, Allergan, Boehringer Ingelheim, Forest, Lilly, Lundbeck, Novonordisk, Pfizer, Sanofi, and Shire Pharmaceuticals

## CASE STUDY: 66 y.o. Gina M

- Obese (BMI = 33.5) Latina, DM-2 X 15 yrs
- DM Meds
  - Metformin 1000 mg b.i.d.
  - Glimepiride 8 mg qd
- Glucose
  - FBS: 160-200 mg/dL
  - Lunch postprandial: 220-300 mg/dL
- Recent ↑ Urinary Frequency (No UTI)
- HbA1c = 9.8

WHAT SHOULD WE DO NEXT?

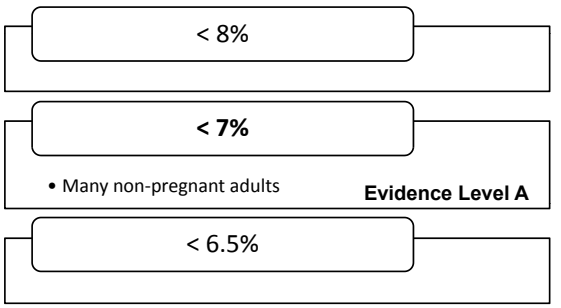
## DM Rx Goal: My Opinion

To maintain the best possible status of glucose control, CV risk factors, and QOL that does not incur an unacceptable counterbalancing burden of adverse effects, costs, or complexity.

## Goals for Our Senior Patients

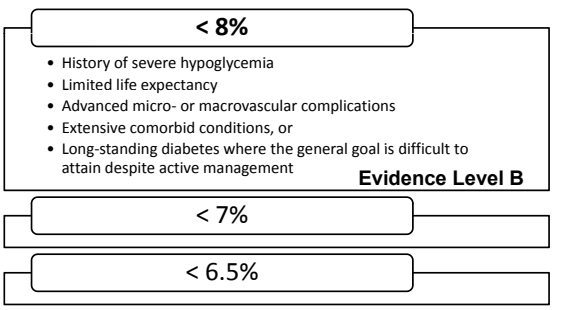
- MACROvascular Risk Reduction
  - MACE (stroke, MI, CHF, ACS)
- MICROvascular Risk Reduction
  - Nephropathy, neuropathy, retinopathy
- Avoidance of hypoglycemia
- Improved QOL
- Minimization of polypharmacy
- Cost-consciousness

## ADA 2017 Recommended A1C Goals




American Diabetes Association. *Diabetes Care.* 2017;40(Suppl1):S48-S56

## ADA 2017 Recommended A1C Goals




American Diabetes Association. *Diabetes Care.* 2017;40(Suppl1):S48-S56

## ADA 2017 Recommended A1C Goals

< 8%

< 7%

**< 6.5%**

- Without significant hypoglycemia or other adverse effects
- Short duration of diabetes
- T2DM treated with lifestyle or metformin only
- Long life expectancy
- No significant CVD

**Evidence Level C**

American Diabetes Association. *Diabetes Care.* 2017;40(Suppl1):S48-S56

## WHAT' s THE PROBLEM?

PROTEINURIA

LIPIDS

GLUCOSE

BP

OBESITY

## Causes of Death in Diabetes

| CAUSE | % of DEATHS |
|---|---|
| • Ischemic Heart Disease | 40% |
| • Other Heart Disease | 15% |
| • Acute Diabetic Complication | 13% |
| • Cancer | 13% |
| • Stroke | 10% |
| • Pneumonia & Influenza | 4% |
| • All others | 5% |

Geiss LS, et al. Diabetes in America 2nd ed. 1995:233-257

## Diabetics: At High Risk for CV Events

Compared to non-diabetics
- 2- to 4-fold greater risk of CVD
- Poorer prognosis for survival
- 3-fold greater mortality from stroke
- ↑ risk of permanent brain damage with carotid emboli

Grundy SM, et al. *Circulation.* 1999;100:1134-1146.
*Diabetes Facts and Figures*. American Diabetes Association, 2000.

## HOW MIGHT WE RE-PRIOTIZE DM-2 MANAGEMENT?

☆ B M I

- #1 BP
- #2 Lipids
- #3 Microalbuminuria
- #4 Glucose

## 66 y.o. Gina M.

- BP 160/98
- HDL 28, LDL 140, TG 220
- Smokes 1 ppd
- 24-hr urine protein = 150 mg/d
- Sedentary
- BMI = obesity

## Goals for Our Senior Patients

- MACROvascular Risk Reduction
  - MACE (stroke, MI, CHF, ACS)
- MICROvascular Risk Reduction
  - Nephropathy, neuropathy, retinopathy
- Avoidance of hypoglycemia
- Improved QOL
- Minimization of polypharmacy
- Cost-consciousness

## Glycemic Goals: Older Adults

"There are few data specifically addressing optimal glycemic goals in medication-treated older patients."

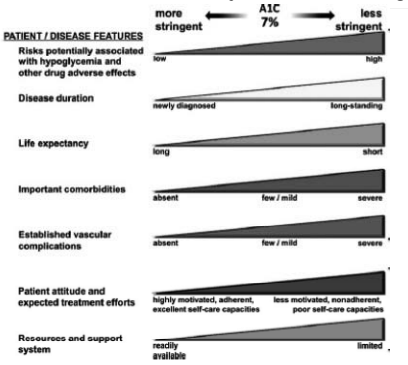
McCulloch DK Rx of T2DM in the older patient UpToDate Updated 3/9/16

## Glycemic Goals: Older Adults

| Older Group | A1c | FPG/Preprandial |
|---|---|---|
| Fit Older Adults | <7.5 | 140-150 mg/dL |
| Frail Older Adults | ≤8% | 160-170 mg/dL |
| Very Old Adults | <8.5% | (Average <200 mg/dL) |

McCulloch DK Rx of T2DM in the older patient UpToDate Updated 3/9/16

## Individualization of Glycemic Targets



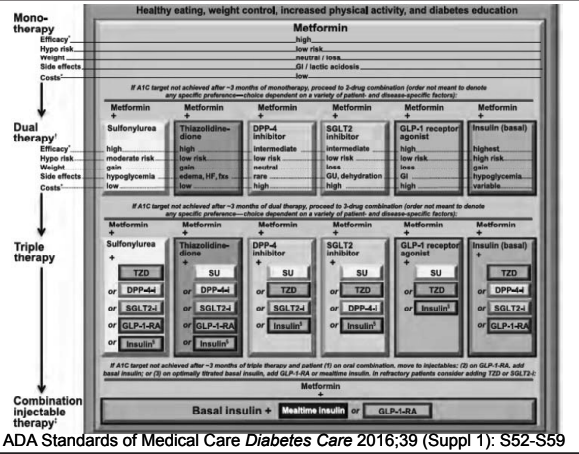

ADA Standards of Medical Care 2016 Diabetes Care 2016;39(Suppl 1):S39-S46

## CASE STUDY: 66 y.o. Gina M

- Obese (BMI = 33.5) Latina, DM-2 X 15 yrs
- DM Meds
  - Metformin 1000mg b.i.d.
  - Glimepiride 8 mg qd
- Glucose
  - FBS: 160-200 mg/dL
  - Lunch postprandial: 220-300 mg/dL
- HbA1c = 10.2

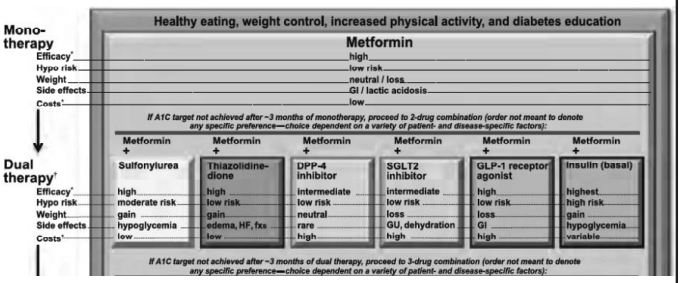
WHAT SHOULD WE DO NEXT?

**BASAL INSULIN**

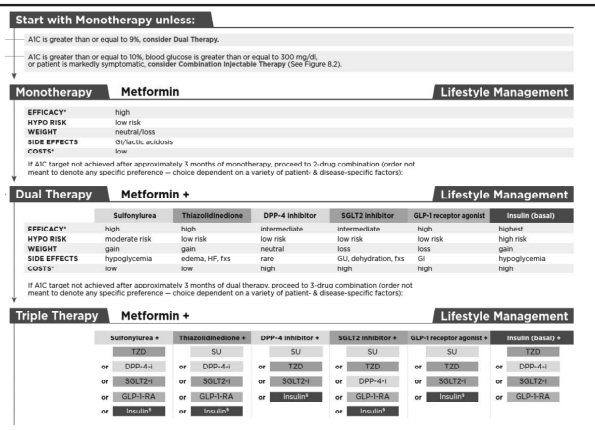



ADA Standards of Medical Care *Diabetes Care* 2016;39 (Suppl 1): S52-S59

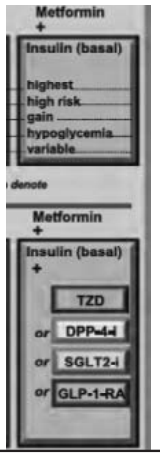
## Pharmacotherapy ADA 2016




ADA Standards of Medical Care *Diabetes Care* 2016;39 (Suppl 1): S52-S59




American Diabetes Association. *Diabetes Care.* 2017;40(Suppl1):S64-S74




ADA Standards of Medical Care *Diabetes Care* 2016;39 (Suppl 1): S52-S59

## Hypoglycemia Caution: Cognitive Function

"It is important to prevent hypoglycemia to reduce the risk of cognitive decline…"

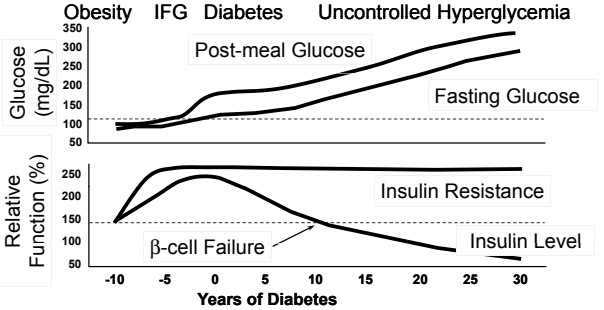
ADA Standards of Medical Care *Diabetes Care* 2016;39 (Suppl 1): S81-S85

## WHY BASAL INSULIN?

- A1c >9.5: other monotherapy agents unlikely to attain A1c goal
- Pt is symptomatic
- FFF model
- >60% of metformin patients may attain and maintain A1c goal ≤7% with basal insulin alone for at least 3 years*

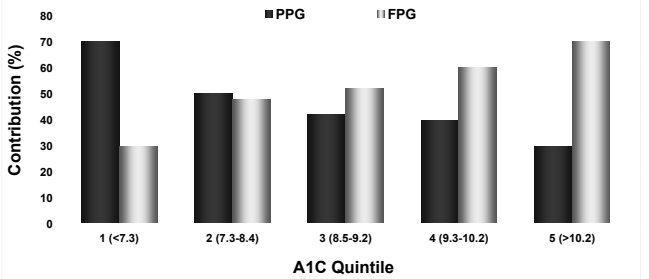
*Holman RR et al Three- Year Efficacy of Complex Insulin Regimens in T2DM" NEJM 2009;361(18):1736-

## Natural History of Type 2 Diabetes




Adapted from International Diabetes Center, Minneapolis, MN; DeFronzo RA. *Ann Intern Med.* 1999;131:281-303.

## FFF: Relative Contributions of PPG and FPG to A1c




Monnier L et al *Diabetes Care* 2003;26:881-885

## Basal Insulin Titration Methods

| | 2-4-6-8 | 2 Q 3 | 1Qd |
|---|---|---|---|
| Starting dose | 10 u | 10 u | 10 u |
| Test Frequency | 1 X/wk | Q 3 days | daily |
| #tests/month | 4 | 10 | 31 |
| Metric | Avg FBG Sat/Sun | Avg FBG q 3 days | FBG |
| Trial | Treat-to-Target | | INSIGHT |

## Evidence-Based Insulin Titration Schedule

| FBG for 3 consecutive days | Basal Dose Adjustment |
|---|---|
| >180 mg/dL | +8 units |
| 160 - 180 mg/dL | + 6 units |
| 140 - 160 mg/dL | +4 units |
| 120 – 140 mg/dL | +2 units |
| 110 – 119 mg/dL | +1 unit |
| 80 – 99 mg/dL | Maintain Dose |
| 60-79 mg/dL | -2 units |
| <60 mg/dL | -4 units |

## Gina M: 3 months later

- DM Meds
  - Metformin 1000mg b.i.d.
  - Glimepiride 8 mg qd stopped
  - Basal insulin titrated to 40 units QAM
- Glucose
  - FBS: 120-130 mg/dL
  - PPG (breakfast/lunch): 150-180 mg/dL
  - PPG (dinner): 220-300 mg/dL
- BMI ↑: 33.5 → 35
- A1c: 8.1

WHAT SHOULD WE DO NEXT?

## Gina: Goal A1c 7

Step 1 FFF (Metformin + Basal Insulin)
A1c: 10.2 → 8.1

Step 2 Address PPG

| | | |
|---|---|---|
| ~~SGLT2~~ | ~~GLP1-RA~~ | ~~RAI~~ |
| ~~DPP4~~ | ~~TZD~~ | ~~AGI~~ |

**Safety and efficacy of a glucagon-like peptide-1 receptor agonist added to basal insulin therapy versus basal insulin with or without a rapid-acting insulin in patients with type 2 diabetes: results of a meta-analysis**

Carol H. Wysham[a], Jay Lin[b] and Louis Kuritzky[c]

[a]Rockwood Clinic, Spokane, WA, USA; [b]Novosys Health, Green Brook, NJ, USA; [c]Department of Community Health and Family Medicine, University of Florida, Gainesville, FL, USA

**ABSTRACT**

**Objective**: To consolidate the evidence from randomized controlled trials evaluating the use of glucagon like peptide-1 receptor agonists (GLP-1 RAs) as add-on to basal insulin therapy in type 2 diabetes (T2D) patients.

**Research design and methods**: We searched the EMBASE® and NCBI PubMed (Medline) databases and relevant congress abstracts for randomized controlled trials evaluating the efficacy and safety of GLP-1 RAs as add-on to basal insulin compared with basal insulin with or without rapid-acting insulin (RAI) through 23 May 2016. The pooled data were analyzed using a random-effects meta-analysis model. A subanalysis was performed for trials investigating basal insulin plus GLP-1 RAs versus basal insulin plus RAI.

**Results**: Of the 2617 retrieved records, 19 randomized controlled trials enrolling 7,053 patients with T2D were included. Compared with basal insulin ± RAI, reduction in glycated hemoglobin (HbA1c) from baseline (difference in means; −0.48% [95% confidence interval (CI), −0.67 to −0.30]; $p < 0.0001$) and weight loss (−2.60 kg [95% CI, −3.32 to −1.89]; $p < 0.0001$) were significantly greater with basal insulin plus GLP-1 RA. The subanalysis similarly showed significant results for change in HbA1c from baseline and for weight loss, as well as a significantly lower risk of symptomatic hypoglycemia in patients treated with basal insulin plus GLP-1 RA versus basal insulin plus RAI (odds ratio, 0.52 [95% CI, 0.42 to 0.64]; $p < 0.0001$).

**Conclusions**: Addition of GLP-1 RA to basal insulin provided improved glycemic control, led to weight reduction and similar hypoglycemia rates versus an intensified insulin strategy; however, symptomatic hypoglycemia rates were significantly lower when compared with a basal insulin plus RAI.

**ARTICLE HISTORY**
Received 21 December 2016
Accepted 17 February 2017

**KEYWORDS**
GLP-1 receptor agonist; basal insulin; rapid-acting insulin; type 2 diabetes; meta-analysis

## Basal Insulin Add-On: GLP-RA vs RAI

**Conclusions:** Addition of GLP-1RA to basal insulin provided improved glycemic control, led to weight reduction and similar hypoglycemia rates versus an intensified insulin strategy; however, symptomatic hypoglycemia rates were significantly lower when compared with a vassal insulin plus RAI.

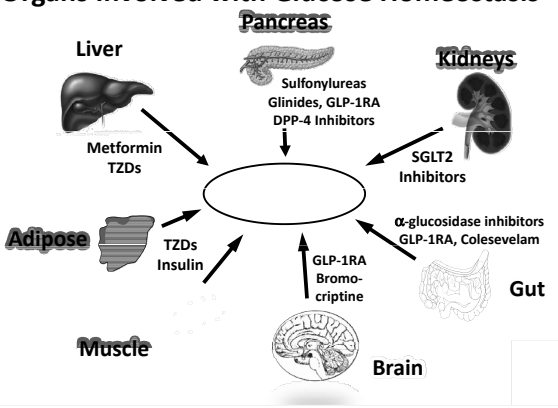
Wysham CH, Lin J, Kuritzky L Postgraduate Medicine 2017 (in Press)

## Causes of Death in Diabetes

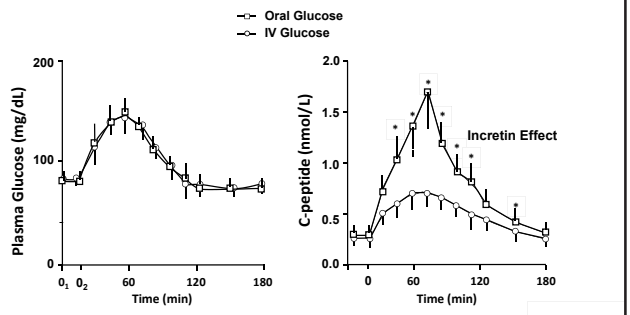
| CAUSE | % of DEATHS |
|---|---|
| • Ischemic Heart Disease | 40% |
| • Other Heart Disease | 15% |
| • Acute Diabetic Complication | 13% |
| • Cancer | 13% |
| • Stroke | 10% |
| • Pneumonia & Influenza | 4% |
| • All others | 5% |

Geiss LS, et al. Diabetes in America 2nd ed. 1995:233-257

## Organs Involved with Glucose Homeostasis




## The Incretin Effect in Healthy Subjects




Mean ± SE; N = 6; *$P \leq .05$; $0_1$-$0_2$ = glucose infusion time.

Nauck MA, et al. *J Clin Endocrinol Metab.* 1986;63:492-498.

## The 'Magic' of GLP-1 Physiologic Effects of GLP-1

- Blunted glucagon secretion
- Augmented glucose-dependent insulin secretion
- Enhanced satiety
- Modulation of gastric emptying

Gallwitz B Int J Clin Pract 2006;60(12):1654-1661

## GLP1 Benefit #1 Blunted Glucagon Secretion

- Alpha cell function is impaired in T2DM
  - Glucagon should only be elevated when glucose is low
  - In T2DM, FASTING glucagon levels are elevated[1]
  - In T2DM, glucagon levels RISE after a meal (→ worsening hyperglycemia)[1]

[1]Del Prato S et al *Horm Metab Res* 2004;36:775–781

## GLP1 Benefit #2
### Enhances Glucose Dependent Insulin Secretion

- Insulin secretagogues (eg, sulfonylurea)
  - Stimulate insulin secretion irrespective of ambient glucose levels
  - Continue to stimulate insulin secretion in the face of hypoglycemia
  - Long-acting agents can → protracted episodes of hypoglycemia
- GLP1→ insulin secretion ONLY when glucose elevated: minimizes hypoglycemia

Drucker DJ Diabetes Care 2003;26:2929-2940

## GLP1 Benefit #3
### Improved Satiety

- Believed to be a CNS effect
- Associated with WEIGHT LOSS
- Weight loss NOT attributable to nausea
- Similar weight loss NOT seen with DPP4

Meier JJ, Nauck MA Best Pract Res Clin Endocrinol Metab 2004;18:587-606

## GLP1 Benefit #4
### Modulation of Gastric Emptying

- 1st-Phase insulin (preformed) absent in T2DM[1]
- Dietary CHO ingestion → exaggerated plasma glucose from to sluggish insulin response due to absent preformed insulin
- Delay in delivery of gastric contents to intestine allows sluggish β-cell better provision of insulin
- Alpha glucosidase inhibitors have favorable glucose effects simply by slowing glucose absorption

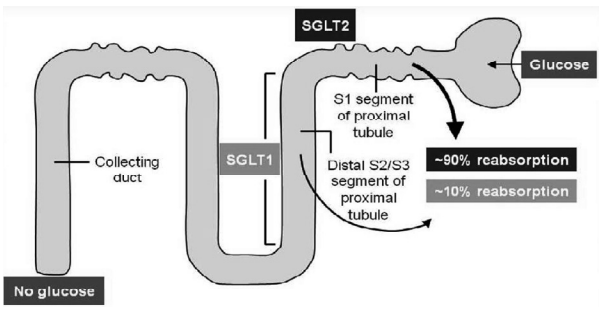
[1]Marchetti P et al *J Clin Endocrinol Metab* 2004;89:5535–5541

## GLP-1R Agonists vs DPP-4 Inhibitors

| Property/Effect | GLP-1R Agonists | DPP-4 Inhibitors |
|---|---|---|
| **Mechanism of action** | GLP-1R Agonist | Inhibits incretin degradation |
| **Route of administration** | Subcutaneous | Oral |
| **A1C lowering** | Up to 1.5% | Up to 1% |
| **Slows gastric emptying** | Yes | No |
| **Promotes satiety** | Yes | No |
| **Weight** | Decreased | Neutral |

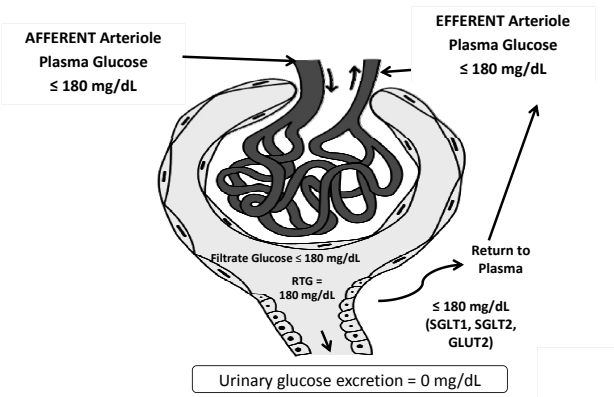
Drucker DJ. *Cell Metab*. 2006 Mar;3(3):153-165.
Lund A, et al. *Eur J Intern Med*. 2014;25(5):407-414.
Neumiller JJ. *Clin Ther*. 2011;33(5):528-576.

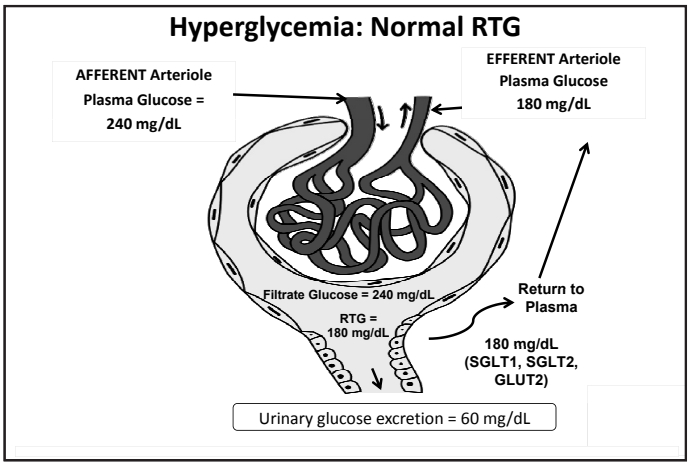
## Targeting the Kidney:
### SGLT2 Inhibition (Canagliflozin)

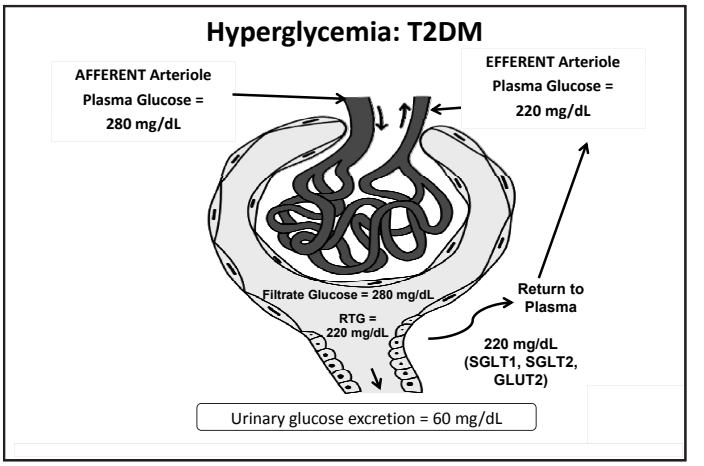


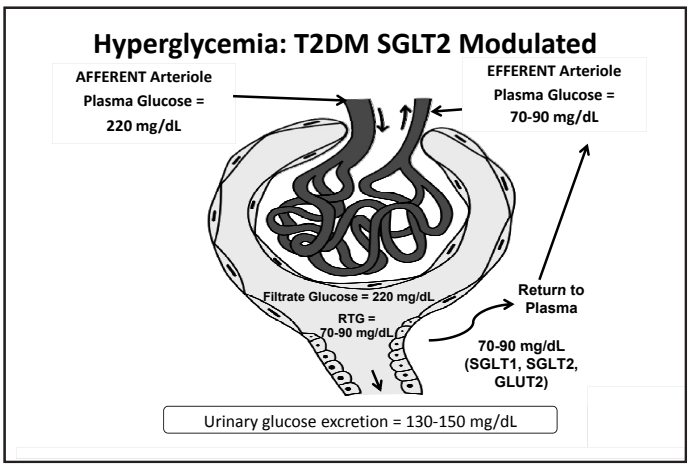

Chao EC, et al. *Nat Rev Drug Discovery*. 2010;9:551-559.

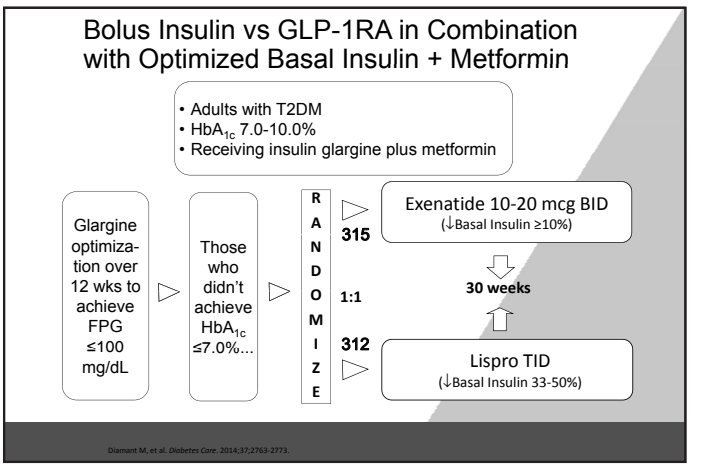
## Normal Glucose: Normal Threshold

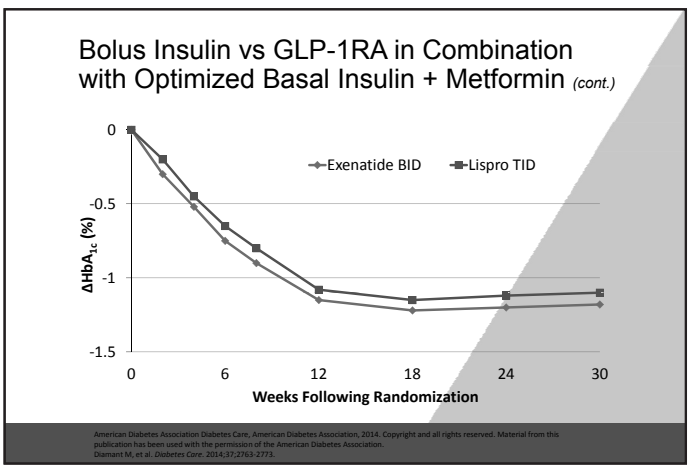


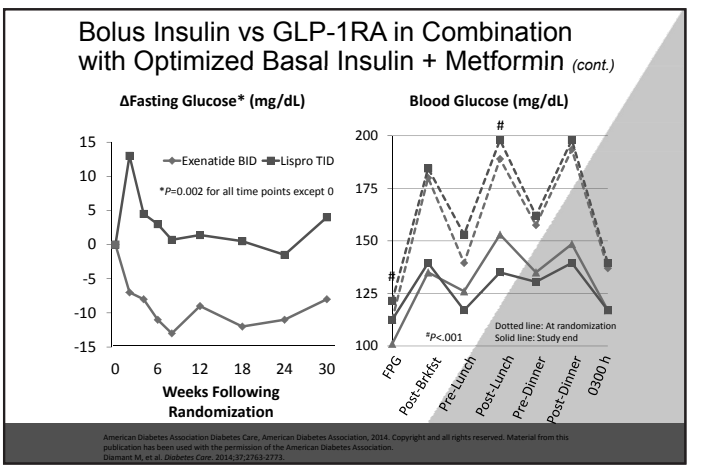

Hyperglycemia: Normal RTG
AFFERENT Arteriole
Plasma Glucose =
240 mg/dL
EFFERENT Arteriole
Plasma Glucose
180 mg/dL
Filtrate Glucose = 240 mg/dL
RTG =
180 mg/dL
Return to
Plasma
180 mg/dL
(SGLT1, SGLT2,
GLUT2)
Urinary glucose excretion = 60 mg/dL


Hyperglycemia: T2DM
AFFERENT Arteriole
Plasma Glucose =
280 mg/dL
EFFERENT Arteriole
Plasma Glucose =
220 mg/dL
Filtrate Glucose = 280 mg/dL
RTG =
220 mg/dL
Return to
Plasma
220 mg/dL
(SGLT1, SGLT2,
GLUT2)
Urinary glucose excretion = 60 mg/dL

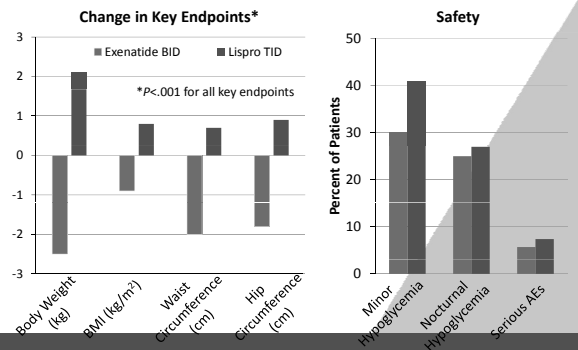

Hyperglycemia: T2DM SGLT2 Modulated
AFFERENT Arteriole
Plasma Glucose =
220 mg/dL
EFFERENT Arteriole
Plasma Glucose =
70-90 mg/dL
Filtrate Glucose = 220 mg/dL
RTG =
70-90 mg/dL
Return to
Plasma
70-90 mg/dL
(SGLT1, SGLT2,
GLUT2)
Urinary glucose excretion = 130-150 mg/dL


Bolus Insulin vs GLP-1RA in Combination
with Optimized Basal Insulin + Metformin
• Adults with T2DM
• HbA1c 7.0-10.0%
• Receiving insulin glargine plus metformin
Glargine optimization over 12 wks to achieve FPG ≤100 mg/dL
Those who didn't achieve HbA1c ≤7.0%...
RANDOMIZE
315
1:1
312
Exenatide 10-20 mcg BID
(↓Basal Insulin ≥10%)
30 weeks
Lispro TID
(↓Basal Insulin 33-50%)
Diamant M, et al. Diabetes Care. 2014;37:2763-2773.


Bolus Insulin vs GLP-1RA in Combination
with Optimized Basal Insulin + Metformin (cont.)
Exenatide BID
Lispro TID
ΔHbA1c (%)
0
-0.5
-1
-1.5
0
6
12
18
24
30
Weeks Following Randomization
American Diabetes Association Diabetes Care, American Diabetes Association, 2014. Copyright and all rights reserved. Material from this publication has been used with the permission of the American Diabetes Association.
Diamant M, et al. Diabetes Care. 2014;37:2763-2773.

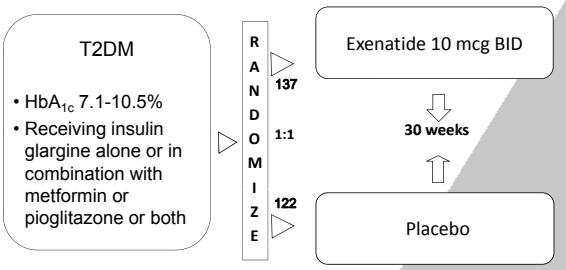

Bolus Insulin vs GLP-1RA in Combination
with Optimized Basal Insulin + Metformin (cont.)
ΔFasting Glucose* (mg/dL)
Exenatide BID
Lispro TID
*P=0.002 for all time points except 0
15
10
5
0
-5
-10
-15
0
6
12
18
24
30
Weeks Following
Randomization
Blood Glucose (mg/dL)
200
175
150
125
100
#
#P<.001
Dotted line: At randomization
Solid line: Study end
FPG
Post-Brkfst
Pre-Lunch
Post-Lunch
Pre-Dinner
Post-Dinner
0300 h
American Diabetes Association Diabetes Care, American Diabetes Association, 2014. Copyright and all rights reserved. Material from this publication has been used with the permission of the American Diabetes Association.
Diamant M, et al. Diabetes Care. 2014;37:2763-2773.

## Bolus Insulin vs GLP-1RA in Combination with Optimized Basal Insulin + Metformin *(cont.)*



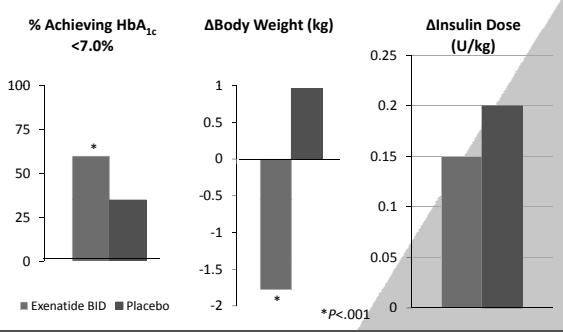

Diamant M, et al. *Diabetes Care.* 2014;37:2763-2773.

## Exenatide BID vs. Placebo Add-on Therapy to Insulin Glargine + Oral Agents




Buse JB, et al. *Ann Intern Med.* 2011;154:103-112.

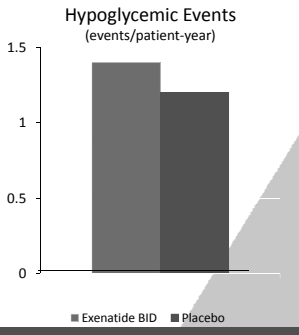
## Exenatide BID vs. Placebo as Add-on Therapy to Insulin Glargine + Oral Agents *(cont.)*




Buse JB, et al. *Ann Intern Med.* 2011;154:103-112.

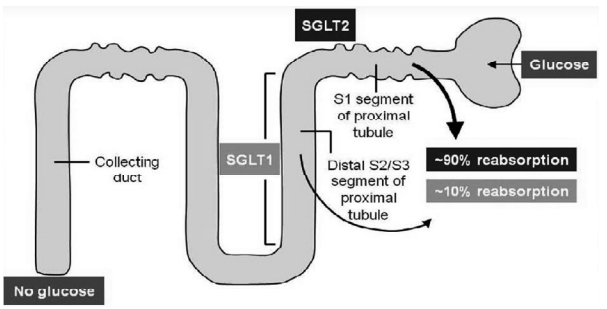
## Exenatide BID vs. Placebo as Add-on Therapy to Insulin Glargine + Oral Agents *(cont.)*

There were no episodes of major hypoglycemia (blood glucose < 54 mg/dL resulting in loss of consciousness or seizure responding to glucose/glucagon, or requiring assistance)




Buse JB, et al. *Ann Intern Med.* 2011;154:103-112.

## Targeting the Kidney: SGLT2 Inhibition (Canagliflozin)




Chao EC, et al. *Nat Rev Drug Discovery.* 2010;9:551-559.

## ASPIRIN Secondary Prevention

Whether or not you have DM

"The merits of daily aspirin therapy in patients with existing CVD are widely accepted."

McCulloch DK Overview of medical care in adults with DM UpToDate Updated 3/9/16

## ASPIRIN SECONDARY Prevention

"For $2^0$ prevention of CVD in patients with DM, we recommend aspirin 75-162 mg/d"

McCulloch DK Overview of medical care in adults with DM UpToDate Updated 3/9/16

## ASPIRIN PRIMARY Prevention

"For $1^0$ prevention of CVD in patients with DM at ↑ CVD risk (10 yr risk >10%) we suggest aspirin (75-162 mg/d), although the evidence supporting this approach is weak."

McCulloch DK Overview of medical care in adults with DM UpToDate Updated 3/9/16

## ASPIRIN $1^0$ Prevention in DM

| | n | f/u yrs | ASA mg/d | CV RR | p |
|---|---|---|---|---|---|
| Primary Prevention Project | **1,031** | 3.7 | 100 | 0.9 | NS |
| Early Rx DM Retinopathy | 3,711 | 3-8 | 650 | 0.83 | NS |
| POPADAD | 1,276 | 6.7 | 100 | 0.98 | NS |
| Japanese PPP | ±5/14K | 5 | 100 | 0.89 | NS |

McCulloch DK Overview of medical care in adults with DM UpToDate Updated 3/9/16

## ASPIRIN in Diabetes: NOT

"Thus, trials in patients with diabetes do not show a significant benefit of aspirin for the primary prevention of CV events."

McCulloch DK Overview of medical care in adults with DM UpToDate Updated 3/9/16

## Primary Care Eye Stuff NHANES

- 11% DM adults visual acuity <20/40 (best eye, corrected if applicable)
- Correctable in 2/3

MMWR 2006;55:1169

## Primary Care Eye Stuff NHANES

" Health-care providers…should be more aware that poor vision often is correctable and that visual corrections can reduce the risk for injury and improve the quality of life for persons with diabetes."

MMWR 2006;55:1169

## Which of the Following Has the Best Predictive Value for Diagnosing DPN?

- Monofilament
- Tuning Fork 128 Hz
- Tuning Fork 512 Hz
- Skin Temperature
- Ankle Reflex
- Ouija Board

## "Back to Basics in Diagnosing Diabetic Polyneuropathy with the Tuning Fork!"

Meijer JWG, et al Diabetes Care 2005;28(September):2201-2205

## Diabetic Polyneuropathy STUDY OBJECTIVE

"Several national and international scoring systems are used to Dx DPN. The variety in these scores and the lack of data on validity and predictive value has led [us] to a comparison and validation...to determine the most powerful measurement for screening."

Meijer JWG, Smit AJ, Lefrandt JD, et al "Back to Basics in Diagnosing Diabetic Polyneuropathy with the Tuning Fork!" Diabetes Care 2005;28:2201-2205

## Diagnosing DPN: Study Design

- 3 matched groups
  - DMs with neuropathic foot ulcers (n=24)
  - DMs without known DPN or ulcers (n=24)
  - Nondiabetics (n=21)

Meijer JWG, Smit AJ, Lefrandt JD, et al "Back to Basics in Diagnosing Diabetic Polyneuropathy with the Tuning Fork!" Diabetes Care 2005;28:2201-2205

## Diagnosing DPN: Dx Tools

- SCORES (All Participants):
  - International Consensus of the Diabetic Foot (ICDF)
  - Dutch Netherlands Diabetes Federation Score
  - Diabetic Neuropathy Symptom Score
  - Diabetic Neuropathy Examination Score
  - Heart Rate Variability
  - Nerve Conduction Sum Score
  - San Antonio Consensus Sum Score

Meijer JWG, Smit AJ, Lefrandt JD, et al "Back to Basics in Diagnosing Diabetic Polyneuropathy with the Tuning Fork!" Diabetes Care 2005;28:2201-2205

## Diagnosing DPN Results & Conclusions

- "The predictive value was good for all scores, with the best results being obtained for the tuning fork"
- "The single use of the 128-Hz tuning fork produces results…much better than those of monofilaments on validation and for predictive value."
- "For screening, we therefore advise the use of the tuning fork alone."

Meijer JWG, Smit AJ, Lefrandt JD, et al "Back to Basics in Diagnosing Diabetic Polyneuropathy with the Tuning Fork!" Diabetes Care 2005;28:2201-2205

## Summary: DM Older Adults

- Flexible A1c Goals
- Recognition of multiple GLP roles
- Harnessing Renal Excretion: SGLT2-i
- BP and Lipid prioritization
- Feet
- Vision
- It takes a village

## SELF EVALUATION

### Managing Type 2 Diabetes in Older Adults

**1.** According to the ADA (2017), an appropriate A1c goal for most non-pregnant T2DM adults is?

a. ≤ 6.0%
b. ≤ 6.5%
c. ≤ 7.0%
d. ≤ 8.0%

**2.** According to the ADA (2017) an appropriate A1c goal for a young patient with recent onset T2DM is?

a. ≤ 6.0%
b. ≤ 6.5%
c. ≤ 7.0%
d. ≤ 8.0%

**3.** According to the ADA (2017), an appropriate A1c goal for an older patient having difficulty achieving A1c goals or experiencing severe hypoglycemia is

a. ≤ 6.0%
b. ≤ 6.5%
c. ≤ 7.0%
d. ≤ 8%

**4.** CV deaths are responsible for what percent of deaths in diabetics

a. 20%
b. 30-40%
c. About 50%
d. At least 65%

**5.** Which agent is most likely to attain goal A1c ≤ 7.0 in an adult T2DM patient has an A1c of 9.5 on maximum metformin and a sulfonylurea (e.g.,, glimepiride)

a. Basal insulin (e.g., degludec, detemir, glargine)
b. An SGLT2 inhibitor (e.g., canagliflozin, dapagliflozin, empagliflozin)
c. A GLP1-RA (e.g., albiglutide, dulaglutide, exenatide)
d. A DPP4-i (e.g., alogliptin, linagliptin, saxagliptin

**6.** The effect of a GLP1-RA on glucagon is

a. Glucagon is blunted, in a glucose-dependent fashion
b. Glucagon is blunted, regardlessof ambient glucose
c. There is no meaningful effect upon glucagon
d. Glucagon secretion is enhanced, in a glucose dependent fashion

**7.** SGLT-2 inhibitors reduce glucose by

a. Blocking glucose reabsorption in the proximal tubule of the kidney
b. Inhibiting hepatic gluconeogenesis
c. Blocking gastrointestinal glucose absorption
d. Inhibiting adipose compartment triglyceride generation

**Answer Key:** 1. C, 2. B, 3. D, 4. D, 5. A, 6. A, 7. A

## Rabbi Elimelech Goldberg

Rabbi Elimelech Goldberg, of Southfield, Michigan, is a clinical assistant professor in the Department of Pediatrics of Wayne State University School of Medicine in Detroit, Michigan. His focus on teaching simple pain and stress reduction tools benefitting physician and patient alike is the subject of many medical grand rounds the Rabbi has presented in leading hospitals around the globe. This methodology is an off shoot of his work as the founder and international director of Kids Kicking Cancer, an organization that lowers the pain of over 3,500 children a year in 45 hospitals. Rabbi Goldberg is a First Degree Black Belt in Choi Kwang Do who, after losing his first child to leukemia at the age of two, merged modern integrative medicine with traditional martial arts to addresses the overwhelming needs of children with illness.

You may contact Rabbi Goldberg with your questions and comments at 248-864-8238, or by email at RabG@KidsKickingCancer.org.

Kids Kicking Cancer
Power Peace Purpose

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# Non-pharmacologic Pain Management Techniques

***Rabbi Elimelech Goldberg***

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## Goals

1- Introduce you to the children of Kids Kicking Cancer who will both help to teach this seminar and in turn be positively impacted by this presentation.

2- Review some of the pain theories that shape our current therapeutic practices.

3-Teach you simple pain management techniques that will be simple and time effective in passing on to your patients.

4-Teach you how to create greater patient compliance in their pain management.

5- Demonstrate the therapeutic benefits of integrating an ontological approach with your patients.

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The adrenal gland is an essential stress-responsive organ that is part of both the hypothalamic-pituitary-adrenal axis and the sympatho-adrenomedullary system. Chronic stress exposure commonly increases adrenal weight. The onslaught of glucocorticoids can adversely affect myriad aspects of our health.

"Chronic stress induces adrenal hyperplasia and hypertrophy in a subregion-specific manner".
Ulrich-Lai YM[1], Figueiredo HF, Ostrander MM, Choi DC, Engeland WC, Herman JP.
Am J Physiol Endocrinol Metab. 2006 Nov;291(5):E965-73. Epub 2006 Jun 13.

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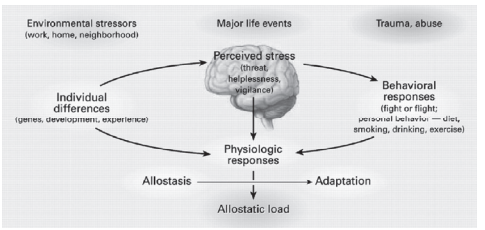
## Allostasis

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Ongoing secretion of glucocorticoids from the adrenal gland can cause a damaging allostatic load on the body.

Allostasis is the body's response to stress in order to maintain homeostasis.

More emphasize today is being placed in medical education on understanding the allostatic load of the patient beyond the biology of response.

Not to be familiar with the major sources of stress in a patient's life robs a physician of profound diagnostic and interventional tools.

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However, beyond the stress implications on morbidity and mortality, stress can significantly influence the perception of pain.

A 2015 study by Prof. Ruth Defrin of the Department of Physical Therapy at TAU's Sackler Faculty of Medicine published in the journal *PAIN* finds that acute psychosocial stress has a dramatically deleterious effect on the body's ability to lower pain perception.

Prof. Defrin, TAU doctoral student Nirit Geva and Prof. Jens Pruessner of McGill University, applied acute stress tests on a large group of healthy young male adults to evaluate the workings of the body's pain modulation mechanisms prior to and after the induction of stress.

The researchers found that there was a significant increase in pain intensification and a decrease in pain inhibition capabilities.

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## Descartian Model of Pain

Latin for pain is *poena* or punishment.

Assumes all pain is injury with a direct relationship between damage and harm

Leads to overly simplistic and often incorrect treatment

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The historic pain model of a "pain center" in the brain, follows Descarte. Although many still follow that model it is not accurate and can lead to ineffective interventions and worse.

Ronald Melzak was one of the pioneers of discovering the sodium voltage channels that articulate the pain message.

Today we have added other pain channels in our efforts of attempting pharmacological interventions.

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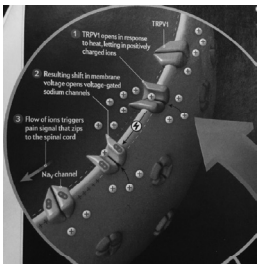
## Transient Receptor Potential Channel Sodium Voltage Channels




Illustration, Emily Cooper Scientific American, December 2014 pg. 63

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## Nociceptive Pain

Somatic Pain

Injury to the skin, muscles, joints, bones, or connective tissue will cause the body to reference somatic pain. If the pain is located deep within the body, it is more likely to be described as dull or aching. If the pain is emanating from the skin layer or just below, it is more likely to be described as sharp, prickly, or burning.

Visceral Pain

When the internal organs and/or their supporting tissues suffer damage, the pain is called visceral. If the injured organ is hollow, like the intestine or gall bladder, the pain is often hard to pin down to a specific location and may feel like cramping. In a non-hollow organ like the liver, the person may experience stabbing pain or deep pressure.

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## Neuropathic Pain

1. pain (constant or intermittent, like shooting or stabbing pain)
2. burning sensation
3. tingling ("pins and needles" feeling) or electric shock–like pain
4. loss of feeling (can be numbness or inability to sense pressure, touch, or temperature)
5. loss of dexterity (e.g., dropping things)
6. balance problems
7. trouble with tripping or stumbling while walking
8. pressure may hurt more than usual
9. temperature may hurt more than usual
10. shrinking muscles
11. muscle weakness
12. difficulty swallowing
13. constipation
14. difficulty urinating
15. change in blood pressure
16. decreased or lack of reflex response

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## Psychogenic Pain

In the absence of identifiable physical causes that underlie the perception of pain, it is possible to arrive at the conclusion that the pain is generated by psychological causes rather than specific receptors in the nervous system signaling the presence of danger to the body.

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In 1999 Melzak introduced the "Neruomatrix of Pain"

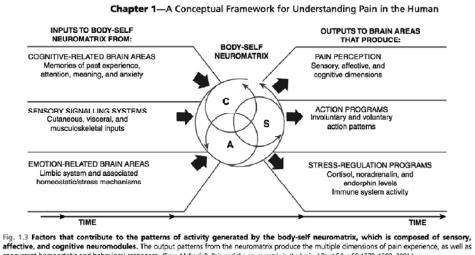


Fig. 1.3 **Factors that contribute to the patterns of activity generated by the body-self neuromatrix, which is composed of sensory, affective, and cognitive neuronodules.** The output patterns from the neuromatrix produce the multiple dimensions of pain experience, as well as concurrent homeostatic and behavioral responses. *(From Melzack R: Pain and the neuromatrix in the brain. J Dent Educ 65:1378–1382, 2001.)*

IMAGE: Updated Neuromatrix Model. Waldman SD: Pain Management, 2nd Ed. (Saunders) 2011
p. 5. Ch. 1: A Conceptual Framework for Understanding Pain in the Human. Joel Katz and Ronald Melzack

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An estimated 100 million people suffer from chronic pain mostly as back pain, headaches or arthritis. This affects more people than cancer, diabetes and heart disease combined

Institute of Medicine Report from the Committee on Advancing Pain Research, Care, and Education: *Relieving Pain in America, A Blueprint for Transforming Prevention, Care, Education and Research*. The National Academies Press, 2011.

17.6% of the population experiences some form of moderate to severe chronic pain. That represents 40 million people.

National Health Interview, 2012 National Institute of Health

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More than half of respondents (51%) felt they had little or no control over their pain.
Six out of ten patients (60%) said they experience breakthrough pain, one or more times daily, severely impacting their quality of life and overall well-being.

Almost two-thirds (59%) reported an impact on their overall enjoyment of life.
More than three quarters of patients (77%) reported feeling depressed.
70% said they have trouble concentrating.
74% said their energy level is impacted by their pain.
86% reported an inability to sleep well.

2006 Voices of Chronic Pain Survey. (American Pain Foundation)

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## "Pain is the fifth vital sign"

In 1996 the American Pain Society (APS) described pain as the "Fifth Vital Sign", an approach accepted by the Department of Veteran Affairs in 1999. It gained growing approbation.

In 2016, the AMA recommended removing pain as a vital sign.

In this shifting environment, doctors have been sued for not giving opioids. Doctors have been sued for prescribing opioids.

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## Opioid Epidemic

The majority of deaths (60%) occur in patients when they are given prescriptions based on prescribing guidelines by medical boards

20% of deaths in low dose opioid therapy of 100 mg of morphine equivalent dose or less per day and 40% in those receiving morphine of over 100 mg per day.

40% of deaths occur in individuals abusing the drugs obtained through multiple prescriptions, doctor shopping, and drug diversion.

Pain Physician. 2012 Jul;15(3 Suppl):ES9-38

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## Duration Neglect

Barbara L. Fredrickson and Daniel Kahneman1993

Looking at patients' perception of pain, indicated that the actual stimulation of pain nerves may be mitigated by the patients' feeling of pain based upon the overall pain experience.

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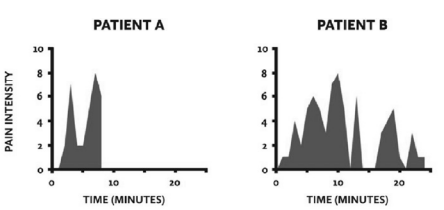
## Peak End Rule

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The pain and stress cycle affect ongoing neurological challenges that self-perpetuate and accentuate, loosening the connection to the pre frontal cortex.

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## Elevated P$_{ain}$S$_{tress}$A$_{nger}$

1. Change in the neuro-chemical environment
2. Weakening of synaptic connections
3. Stress chemicals release from brain stem
4. Glucocorticoids release from adrenal glands
   A. switches off neurons in the prefrontal cortex
   B. primal areas such as basal ganglia ramp up
      - ➢ habitual emotional responses
      - ➢ cravings …. addictive behaviors

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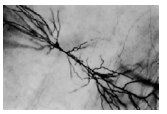
## Pyramidal Cells

Neurological Executive Center Reaches into the deep brain structures that control:



- ➢Emotions
- ➢Desires
- ➢Habits
- ➢Perception
- ➢Focus

Assures the amygdala (fear center) that all is well

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Researchers found that increased expression of PACAP -- a peptide neurotransmitter the body releases in response to stress -- is also increased in response to neuropathic pain and contributes to these symptoms. Using models for chronic pain and anxiety, as well as models that can trace PACAP neurocircuits, the team members were able to observe where the stress and chronic pain pathways intersected. Chronic pain and anxiety-related disorders frequently go hand-in-hand.

"Parabrachial Pituitary Adenylate Cyclase-Activating Polypeptide Activation of Amygdala Endosomal Extracellular Signal–Regulated Kinase Signaling Regulates the Emotional Component of Pain" Victor May, Ph.D., professor of neurological sciences at the University of Vermont (UVM).

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## This is a "TWO"

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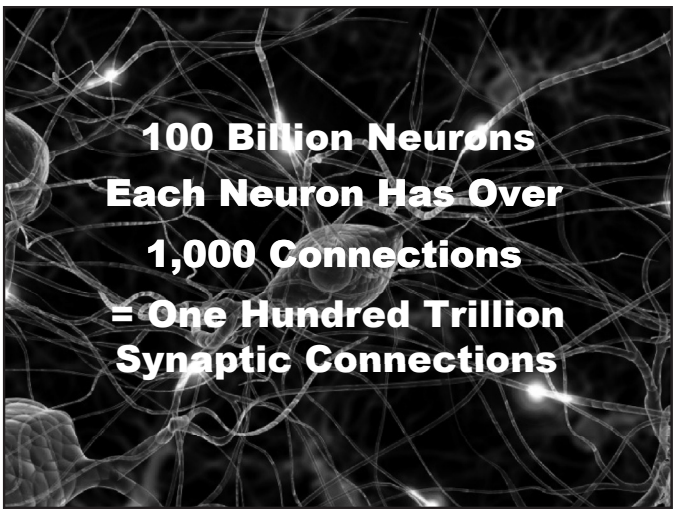
## This is a "TEN"

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## We Become Our Pain

Patients can become defined by their pain.

Pain is often a harbinger of necrosis so it is primed to get a great deal of attention.

However, chronic pain can physically and emotionally cripple a patient.

There is therapeutic value in redefining the ontology of pain into a potentially treatable symptom rather than a definition of "self".

- I have cancer
- I am depressed
- I am angry
- I am short

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## Tension is a Wall

We have a tendency to build protective walls when confronted with pain, both physical and emotional pain.

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## American Institute of Stress

To evaluate the relative stress level of individuals, a group of scientists at the University of Oxford have devised a system that associates hyper-attentiveness with cortisol levels.

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## Power Breathing

The "Breath Brake®" has been used by Kids Kicking Cancer to help establish a sense of control over pain and stress and thus lower patient discomfort.

We published our pain study in the "Journal of Pediatric Health, Medicine and Therapeutics"; Dove Medical Press 201:67, June, 2016

The study followed 64 participants - 43 males 21 females ages 3 to 19 years old observed during 223 individual sessions. We recorded a decrease in pain intensity in 85.3% of visits with overall pre-score pain reduced by 40%.

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The mantra of Kids Kicking Cancer is "Power Peace Purpose" which the children teach to adult patients in many different settings.

"Power" describes the "energy" that we use in the martial arts as a light that we can visualize and bring into our body.

"Peace" refers to the inner calmness that we feel as we blow out pain, fear and anger.

"Purpose" connects to our ability to teach this to the world around us. During our presentations the children yell out that their purpose is to "teach the world."

This impacts the ontology of pediatric illness significantly as quoted above.

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## The "Breath Brake®"

The Kids Kicking Cancer "Breath Brake®" is a very simple intervention to use for yourself and then teach to your patients. (The more you integrate this simple breathing technique for your own life, the greater your passion in teaching it to your patients.)

The first step is to observe that you are experiencing stress. Stress chemicals will cause muscles to become tensile. Train yourself to observe that you are "tight". If you are not exercising at that moment, chances are that your body is responding to stress.

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Breathing is the only part of your autonomic system that you can so easily control.

Using your breath to relax your muscles signals to your brain that you are not in a sympathetic mode.

You can trigger a parasympathetic response using a "Breath Brake®".

Directions-

This can be done from any position. The key is to use your breath to move your body like a wave.

Keep it simple. The issue for the "Breath Brake®" is not diaphragmatic breathing. However, you are comfortable breathing is fine. With your inhale, slowly breathing through your nose, lift up your body with the breath. Feel your shoulders lift up, your chin rise and your chest expand upwards. At the end of the breath, pull in a little bit more and hold that for three seconds. When exhaling slowly through your mouth, allow your body to fall in the opposite direction. Feel your chin and shoulders fall, your neck, your shoulders and then your chest. At the very end of that exhale, gently blow out a little more and then relax.

Repeating the "Breath Brake®" every time you feel the tightness of stress and then focusing simply on using the breath to relax the muscles has had a significant impact on the people we have trained.

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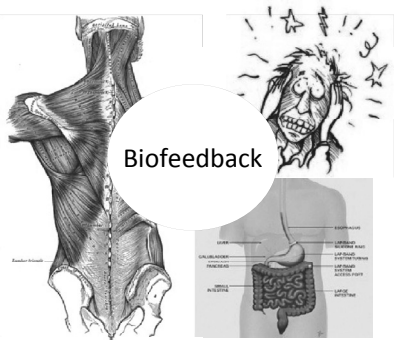


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"Significant evidence exists to support the use of guided imagery in the management of cancer -related pain (acute and chronic), as well as cancer treatment-related anxiety, nausea and vomiting, and depression."

"Guided Imagery for Pain Control" Peggy Burhenn, MS, CNS, AOCNS®, Jill Olausson, RN, MSN, CDE, Griselda Villegas, RN, OCN®, and Kathy Kravits, MA, RN, HNB-BC, LPC, NCC, ATR-BC "Clinical Journal of Oncology Nursing" Volume 18, Number 5. October 2014

The martial arts is very focused on imagery. Before karate masters will break a brick or series of boards, they image the target being destroyed. Creating a similar pathway for pain management employs the conceptual framework of the neuro-matrix.

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The exercise is best kept very simple. Ask the patient to describe how large the pain is and what color he or she imagines it to be. (We have found that for inflammatory pain, most of our participants answer, "red".) Ask them to imagine that redness as a ball or a fist. (In the martial arts, there is a great deal of focus on our breath coming from different parts of our body.) Request from the patient to imagine the breath coming from right below the pain and as it precedes upward, making small holes in the worst part of the pain. (We have various meditations accessible through my book that create meditations around this theme. – I don't know what you want to do with that but the book is accessible on www.kkcbook.org) Continue that breathing, slowly but rhythmically, only in a manner that the patient is comfortable. At the exhale, the patient is asked to see him or her blowing out the redness as a cloud out of his or her mouth. Allow the patient, if he or she is able to add color to that light to see if it is effective. But also allow the patient to thank the children of Kids Kicking Cancer if this works for them (this creates great incentive to keep trying) On the books website, www.kkcbook.org one can thank the children for these lessons even without purchasing the book or on our kkc contact page www.kidskickingcancer.org

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## Push Is Weak – Pull is Powerful

In the martial arts, we learn that is someone is pushing you, you don't get very far by pushing back. Push is weak but pull is powerful. It is natural to try to push out against a pain syndrome. The more we can accept that discomfort and pull it in to ourselves with the breath, the greater our opportunity for "blowing out that pain" in our exhale.

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"Optimism does not mean that everything is going to be great. It means that we can respond to everything with greatness!"

A message inspired by Bernard Johnson, age 10

SELF EVALUATION

## Non-pharmacologic Pain Management Techniques

**1.** Stress is linked to
- a. Pain perception
- b. Cancer
- c. Diabetes
- d. Heart disease
- e. All of the above
- f. Some of the above

**2.** Melzak's "Neuro Matrix of Pain Model"
- a. Indicates that there is a well-defined pain center in the brain
- b. Explains the importance of synaptic connections
- c. Is an example of the importance of understanding allostatic load and pain perception
- d. Has been disproven by the presence of sodium channels
- e. All of the above

**3.** Pain is the "fifth vital sign"
- a. Is supported by most acceptable medical associations
- b. Was introduced by the American Pain Society in 1996
- c. Created a standard pain measure
- d. Protects physicians from being sued for prescribing opioids
- e. All of the above

**4.** Duration Neglect
- a. Indicates that people can forget all pain
- b. Was presented by Fredrickson and Kahneman
- c. Indicates peak pain cycles will define pain perception
- d. Requires physicians to report to local Protective Services
- e. Two of the above

**5.** The pain message
- a. Is often a sign of necrotic tissue
- b. Can trigger depression and anxiety
- c. Can define the patient and create chronic disability
- d. All of the above
- e. Two of the above

**6.** Guided imagery
- a. Will power self-driving cars in the near future
- b. Is a simple evidenced based, pain management technique
- c. Requires years of prior meditative practice
- d. Can be introduced only to children
- e. Will always result in happy patients

**7.** The "Breath Brake®" focuses on
- a. Diaphragmatic breathing
- b. Simple breathing technique that moves the body with the breath
- c. Breathing in through the mouth and out through the nose
- d. All of the above
- e. Some of the above

**Answer Key:** 1. E, 2. C, 3. B, 4. B, 5. D, 6. B, 7. B

## Natan Khishchenko M.D., M.B.A.

Natan Khishchenko M.D., M.B.A., of Rochester, New York, is attending neurologist and Neurophysiology Services director for Rochester Regional Health System. In 1999 he received a Masters of Business Administration with a concentration in healthcare management from University of Rochester. Dr. Khishchenko is certified in Basic Life Support and a member of the American Academy of Neurology. He speaks frequently on neurologic issues to both neurologists and non-specialists.

You may contact Dr. Khishchenko with your questions or comments at (585) 441-1062, or by email at Natan.Khishchenko@RochesterRegional.org.

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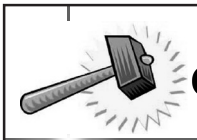
## Understanding and Treating Neurologic Emergencies

# Neurologic Emergencies

Natan Khishchenko, MD



# Goals of Lecture

- Recognize common primary neurologic emergencies seen in community practice
- Understand what makes them acute
  - Presenting sx
  - Areas of nervous system at stake and to what effect
- Relevant portions of history/exam
  - Immediate management issues
  - Whom to call and when
  - Much of M&M comes from medical complications/comorbidities
- Understand that all the other fun and fascinating neuro disorders can wait…

# What This Talk Is Not

- Comprehensive overview of specific classes of disorders
  - Stroke, neuromuscular
- Critical care medicine talk
- Discussion of neuro secondary and/or iatrogenic complications of systemic dz
  - Neuro ID, global anoxia, tetany

# Characteristics of Key Disorders

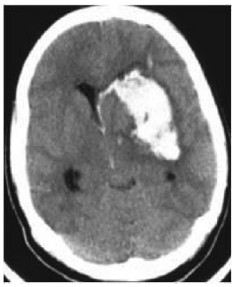
- Acute Onset or Exacerbation
- Focus on small number of classic disorders
- Involve CNS, PNS or both
- Morbidity and/or Mortality
- Localization is key = history/exam
  - Misdx location or organ system leads to other tests (FP/FN issues) and wastes time
  - Paraclin tests help w/ specific dx and prognosis
  - Limited differential typically wisest
  - OK to uprank a less common disease if it can acutely kill you

# CNS vs. PNS

- Brain
- Spinal Cord
- Mass effect lesions
- Vascular supply
- Location & effect:
  - Herniation
  - Obstruction
  - Disruption of primitive functions

- Root/Nerve
- NMJ
- Muscle
- Respiratory function
  - Bulbar
  - Restrictive lung dz
- Peripheral dysautonomia

# CNS Space Occupying Emergencies



## Presenting Features

- UMN hemi motor and/or hemi sensory
- bulbar and/or language
- Visual
- Headache
- decreased level of consciousness
- Sz (primary or 2ary)

- Non vascular d/o (tumors, abscess, demyelination) present acutely d/t location, blood, vasogenic edema (i.e. mass effect)

## The Coma Exam

- The coma history = bystanders, chart review, UTA
- Short, no arguments, same billing:
  - MS, CN, Motor, Sensory all truncated
  - Mental Status = GCS
  - CN = pupils, EOMs, reflexes (doll, corneal, calorics, cough, gag), VII, breathing over vent?
  - M/S: tone, GCS, involuntary
  - Reflexes are reflexes
  - Coordination and gait = UTA
- Glasgow Coma Scale
  - NOT the same as the neuro exam
  - E4, V5, M6 = min is 3; max is 15/11T
  - Focus on primitive survival functions

**Glasgow Coma Scale (GCS)**

| Best eye response (E) | Best verbal response (V) | Best motor response (M) |
|---|---|---|
| 4 Eyes opening spontaneously | 5 Oriented | 6 Obeys commands |
| 3 Eye opening to speech | 4 Confused | 5 Localizes to pain |
| 2 Eye opening in response to pain | 3 Inappropriate words | 4 Withdraws from pain |
| 1 No eye opening | 2 Incomprehensible sounds | 3 Flexion in response to pain |
| | 1 None | 2 Extension to pain |
| | | 1 No motor response |

## Dr K, the CT shows…

- Imaging is key, but you're the doc…
- supports WHERE – did I get the right localization/dx, is it multi focal?
- supports WHAT and guides mgmt
  - Hosp status: home, obs, floors, ICU
  - Rx choices, good and bad: TPA, steroids, BP, etc
  - Surgical involvement?
- supports WHY, depending on study selected:
  - The role of acute CT is to r/o a space occupying process not consisting of dying neurons + their contents
  - CT, MRI, vascular (A/V w/ doppler/TCD, CT, MR, conventional), CT-P, functional (MRS, SPECT, PET)

## Vascular Disorders

- Ischemic stroke – 80-85%: location related issues specific to: large MCA, brainstem, cerebellum
- Hemorrhagic – 15-20%
  - EDH – lucid interval, rapid, MMA, kids, call NSU
  - SDH – can be acute on subacute-chronic, older pts/fall risk, bridging veins, anticoag, etoh abuse
  - SAH – traumatic vs vascular, terrible M&M, CT, LP and/or CTA r/o aneurysm → call NSU
  - ICH – 10%; 30-50% dead 30 days; long term
    - many etiologies, underlying lesion
    - HTN: pons, BG, thalamus, cerebellum (NSU for last one)
    - CAA: lobar or multi lobar, older pts, GRE microbleeds
  - Latter two can be complicated by intra ventricular blood
    - Worsens mortality significantly
    - secondary hydrocephalus

## Vascular D/O Acute Mgmt

<u>Ischemic stroke</u>

- Permissive HTN
  - ? Rx if > 220/120
- ? IV TPA
  - Specific BP goals
- ? Mechanical recanalization
  - IA TPA
  - Thrombectomy
  - 5 trials in 2015

<u>Others</u>

- SBP < 120 ?
  - Prevent hematoma growth
  - No ischemic penumbra
  - STITCH trial
- Reversal of coagulopathy
- ? Surgery depending on type of bleed

## Acute Ischemic Stroke

- Time is Brain!
- NINDS: IV TPA 3hr; 2008 expansion to 4.5hrs (3-4.5hr window overall less successful, incl inc rates of bleeding)
- IA TPA: 6hrs ant circ w/ 8-9hr studies of salvage rx, 12 hrs post circ
- ? over restrictiveness of NINDS criteria
- H/P: rules out mimics
  - don't TPA sz/migraine/psych vs low risk of ICH
  - Imaging helps too: role of CT, ? MR

## Acute Management Issues

- Airway Control – inability to protect, GCS < 8
- ICP (intra cranial pressure) & Herniation Syndromes:
  - Monro-Kelli doctrine
  - CPP = SBP – ICP
  - Trans-falcine, trans-tentorial/uncal, 4th vent
  - Loss of autoregulation/BBB breakdown in injured tissue
  - Med: osmotic agents (mannitol, hypertonic Na = 3% gtt, 23% IVP); ltd by tissue effect, monitor sosm/Na given risks of iatrogenia (central DI)
  - Surg: EVD, hemi-crani (both predominantly for supra tent dz), post fossa decompression (cerebellar bleed or stroke)

## History of Status Epilepticus

- Changing Definition Over Time
  - " … seizure persists for a sufficient length of time or is repeated frequently enough to produce a fixed or enduring epileptic condition… should last at least 30-60 minutes"
  - More than 5 minutes of continuous seizure activity *or* Two or more sequential seizures without full recovery in between them

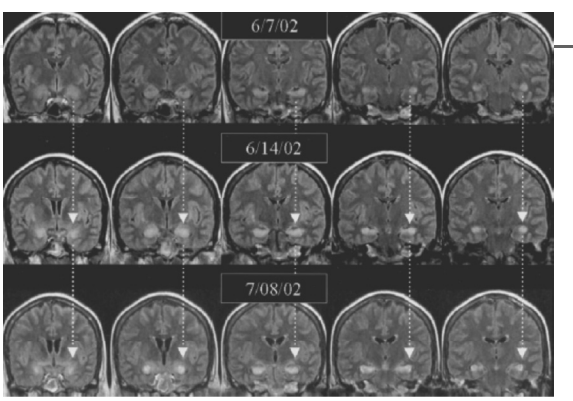
## Acute Management: Pre Hospital

- place patient on their side
- do not restrain or put anything in mouth
- miminize manipulation of cervical spine
- Control of respiratory status
- Administer rescue agent by best available route: po, IM, IV, mucosal (rectal/buccal)
  - RAMPART trial 2012
  - 10mg IM midazolam superior to 4mg IV lorazepam
  - Longer to work vs faster access

## Physiological Changes in GCSE

| Cerebral changes | Metabolic changes | Autonomic changes |
|---|---|---|
| Failure of autoregulation | Hypoglycemia | BP/HR |
| **Hypoxia** | Hyponatremia | Pulmonary edema |
| Hypoglycemia | Hypo/Hyperkalemia | **Arrythmias** |
| Increased lactate | **Acidosis (mixed)** | Hyperpyrexia |
| Increased ICP | Hepatic/Renal dysfunction | |
| Cerebral edema | DIC | |
| | **Rhabdomyolysis** | |
| | Serum/CSF inc WBC | |

## Imaging Evidence of GCSE Damage



## Types of Status Epilepticus and Implications for Management

- **Generalized convulsive SE:**
  - Neurologic emergency
  - Poor prognosis, esp w/ duration > 60 min (mortality inc from 3 to 30+%)
  - Prognosis often linked to underlying condition
  - rx to clinical endpoint, may convert into…
- **Subclinical or subtle SE:**
  - Neurologic emergency
  - partially rx: electromechanical dissociation
  - Burned out GCSE
  - Rx to burst suppression on EEG
- **Non convulsive SE:**
  - Neurologic urgency; might impact morbidity and LOS
  - ICU pt sedated/paralyzed; floor pt w/ persistent AMS
  - Absence SE or CPSE
- **Epilepsia Partialis Continua (EPC) = SPSE**
  - Neurologic urgency

## AEDs for Status Epilepticus

- Benzodiazepines
  - Some studies suggested lorazepam somewhat more efficacious than diazepam
  - Lorazepam has longer T1/2 > midazolam
  - Loading: up to 0.1mg/kg
- IV PHE (Fos), VPA, PHB
  - Fos: inc $, 3x infusion rate, less skin rxn
  - 3 goldie oldies = 20mg/kg initial load, 5-10mg/kg allowed as 2nd load
  - PHB has longest T1/2
  - VPA: 2 positive trials but not FDA approved; good for myoclonic SE
  - LEV (keppra), lacosamide (vimpat) – IV vs. ltd data
- AE: hypotension, resp depression, cardiac arrhythmia
- Gtt: versed, propofol, pentobarb

## VA Cooperative Study: Treiman 1998

- RCT of GCSE & SCSE
- Four treatments & initial success rates:
  - 0.1 mg/kg lorazepam = 65%
  - 15 mg/kg phenobarbital = 58%
  - 18 mg/kg phenytoin = 44%
  - 0.15 mg/kg diazepam + phenytoin 18mg/kg = 56%
  - Success of 2nd line agent only 7%
- Conclusions:
  - Lorazepam is more effective (SS) than phenytoin
  - Equal efficacy between lorazepam, phenobarbital, diazepam with phenytoin

## Status Epilepticus Treatment Algorithm

| Time | Treatment |
|---|---|
| **Onset** | **Ensure adequate ventilation/O2** |
| **2-3 min.** | **IV line with NS, rapid assessment, blood draw** |
| **4-5 min.** | **Lorazepam 2 mg or diazepam 5 mg** |
| **7-8 min.** | **Thiamine 100 mg, 50% glucose 25 mg IV; (Fos)Phenytoin 20 mg/kg IV** |
| **10 min.** | **Can repeat lorazepam to 0.1 mg/kg or diazepam to 0.2 mg/kg** |
| **30-60 min.** | **EEG monitoring unless status ended and patient waking up** |
| **40 min.** | **Phenytoin 5-10mg/kg and/or load Phenobarbital 20 mg/kg** |
| **70 min.** | **Pentobarbital 3-5 mg/kg load, 1 mg/kg/hr infusion** |
| | **OR** |
| | **Propofol 3-5 mg/kg load, 5-10 mg/kg/hr initial infusion** |
| | **OR** |
| | **Midazolam 0.2 mg/kg load, .25-2 mg/kg infusion** |

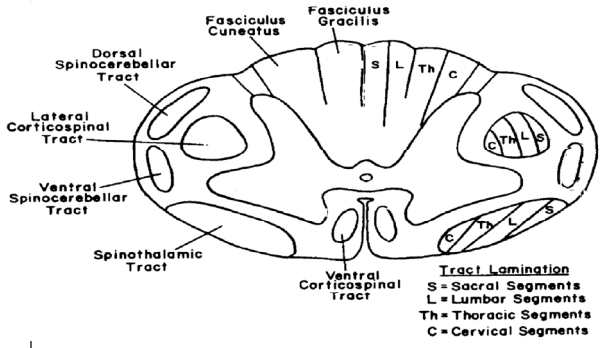
## Spinal Cord Lesions

- History: trauma, vascular dz, surgery
- Localization extra key here
  - ? most often misdz area of neuro dysfuncn
  - What to image and w/ what modality?
- Rule out compressive lesions as mgmt may be surgical:
  - disc/DJD, tumor, hematoma, abscess
- Med mgmt likely supportive (cord infarct) and/or specific to d/o (e.g. demyelination)

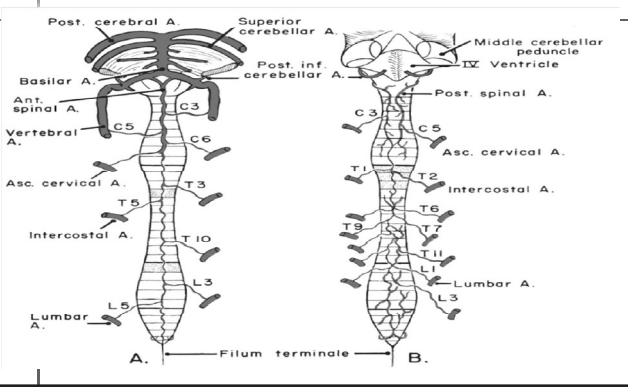
## Is my lesion in the cord?

- UMN or mixed UMN/LMN findings
- Lesion at or above most rostral clinically involved region
- Sensory loss should be dermatomal
- Sparing of cortical functions
- Bowel and bladder incontinence
- Extrinsic compressive lesion affects thickly myelinated fibers first
- Intrinsic lesion affects central structures

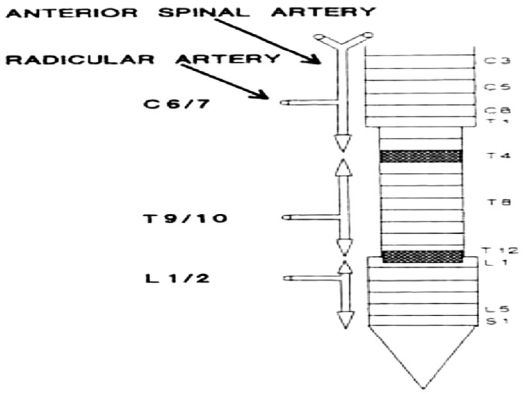
## Spinal cord anatomy




## Vascular (= arterial) supply




## Rostro-caudal watershed zones




## Anterior spinal artery infarct

- Sudden onset
- Anterior 2/3 of the cord
- C3-5: respiratory failure
- T4-9: orthostatic hypotension
  - vasomotor tone splanchic bed affected
- Embolic, iatrogenic

## Where in the cord is it?

- Work your way through the neuro exam…
- Cranial nerve involvement?
- Motor: bulk, tone (acutely flaccid, DRE), power
  - RESPIRATORY FAILURE
- Sensory:
  - Lesion is at **or above** the level of sensory loss
  - Special anatomy of trigeminal nerve
  - Perineal/peri-anal loss
  - AUTONOMIC FAILURE
- Gait: wide base, scissor, astasia abasia
- Reflexes:
  - Most rostral brisk reflex
  - decreased reflex at the level of the lesion
  - Pathologic reflexes: Babinski, Hoffman, jaw jerk, anal wink, bulbo-cavernosus, cremasteric

## Where in the cord is it?: exam limitations syndromes

- Thoracic region:
  - No motor
  - Reflexes: superficial and deep abdominal
  - Beevor's sign
- Sacral region:
  - ? Motor
  - Bowel/bladder
  - Cauda vs. conus
- Brown-Sequard
- Foramen magnum
  - down and out nystagmus
  - lower cranial neuropathies

## PNS Disorders

- Anterior Horn – ALS, West Nile
- Root/Nerve – GBS, porphyria, CCN, toxic/metals
- NMJ – MG, botulism, organophosphate toxicity, hyperMg, iatrogenic (meds)
- Muscle – CCM, rhabdo, acid maltase deficiency, periodic paralyses
- Many belong more to critical care medicine than neuro emergencies: "failure to wean"

## PNS Disorders Presentation

- No UMN findings
- They're in there: quad +/- vent w/ preserved cognition +/- speech
- No bowel/bladder involvement
- Sensory (+/- autonomic), motor or both and pattern of involvement

## Impending Neuromuscular Respiratory Failure

- Quadriplegia
- Neck muscles weak
- Lower CN involvement
- Pnea – tachyp, orthop, dysp
- Can't lift head off bed
- Dysphagia
- Weak/hoarse voice
- Facial diplegia
- Diff w/ secretions
- Accessory/paradoxical abdominal muscles
- Clipped speech/20 ct

## Resp Failure Monitoring

- FVC/NIF
- PO2 – LATE!
- PCO2 – LATE!
- CXR

| | NL | ET tube |
|---|---|---|
| FVC $_{(ml/kg)}$ | > 60 | < 20 |
| NIF $_{(cm\ H2O)}$ | < -70 | -20-30 |

## GBS Dude


## GBS = AIDP

- Most common acquired cause of LMN resp paralysis
- Autoimmune/parainfectious
- Nadir < 4 wks; poor prognosticators include hosp < 7 days, intubation, age > 60, med comorbidities, early axon loss
- Ascending paralysis + sensory loss
- Areflexia
- Classic neurophys features (NCS/EMG)
- M&M d/t resp dysfncn, dysautonomia
- Rx: next pg; steroids don't work

## GBS Treatment Options & Issues

- PLEX
- IV access
- Support svcs
- Hypotension
- Infection
- Duration of Rx
- PLEX → IVIG = NO better than either one
- IVIgG 2.0mg/kg total
- Renal failure
- MI & stroke
- IgA def & anaphylaxis
- Duration of Rx tailored to cardiac/fluid status
- IVIG → PLEX = $$ wasted

## Myasthenia Gravis


## Myasthenia Gravis

- Autoimmune (Ach-R, MuSK)
- diffuse vs proximal weakness
- Bulbar + ocular (diplopia, ptosis)
- Fluctuating diurnal sx/signs
- No sensory symptoms or signs; nl reflexes
- Iatrogenic: mestinon overload, initiation of steroids
- Dx: Ab, NCS/EMG (mostly to r/o other d/o), RNS, SFEMG → CT chest r/o thymoma
- Rx: PLEX (expert opinion preferred) vs IVIgG

## Conclusion

- Neurology is mostly an outpatient driven field, but has emergencies involving all levels of the nervous system
- Neurologic emergencies are common (esp strokes, status), commonly misdiagnosed and/or mistreated
- Neurologic emergencies = significant M&M
- The mgmt of neuro emergencies may have significant areas of unknowns and controversies, but the dx should not
- Understand when and whom to call for help
- If you plan on a career in ED/urgent care, hospital, ICU or clinic, at least know these…
- Information age = anything you don't know in first few minutes, you can quickly look up…

SELF EVALUATION

**Understanding and Treating Neurologic Emergencies**

**1.** True/False - The Glascow Coma Scale is scored out of 15 points

**2.** True/False - The lowest score on the Glascow Coma Scale (GCS) is 0 (zero)

**3.** Strokes subtypes include:

a. ischemic stroke
b. subarachnoid hemorrhage
c. epidural hematoma
d. all of the above

**4.** The most common cause of subarachnoid hemorrhage is:

a. tumor
b. aneurysm
c. ateriovenous malformation
d. stroke

**5.** The mortality of generalized convulsive status epilepticus lasting greater than 60 minutes is:

a. 1%
b. 5%
c. 10%
d. 30%

**6.** Side effects of benzodiazepines used to control seizure include:

a. hypotension
b. respiratory depression
c. cardiac arrhythmias
d. all of the above

**7.** A patient presenting with rapidly ascending weakness, sensory loss and areflexia most likely has:

a. Guillan Barre syndrome
b. Myasthenia gravis
c. Stroke
d. Carpal tunnel syndrome

**8.** A patient with myasthenia gravis may exhibit all of the following signs or synptoms EXCEPT:

a. ptosis
b. diplopia
c. numbness
d. respiratory distress

**ANSWER KEY:** 1. T, 2. F, 3. D, 4. B, 5. D, 6. D, 7. A, 8. C

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**RICHARD A. HONAKER** M.D., F.A.A.F.P.

*Diplomate, American Board of Family Medicine*

## Facilitating Patient Engagement for Better Care

Concepts:

- Generalist (PCP) vs Specialist
- Fee for Service vs Fee for Value (Population Health)
- Volume vs Not Volume
- EMR vs Paper
- Small vs Medium vs Large Practice
- Outpatient vs Inpatient

Always do the right thing and look for right things to do.

Patient Activation

- Patient's knowledge, skills, ability and willingness to manage his/her own health care

Patient Engagement

- Broader concept that combines patient activation with interventions designed to increase activation and promote positive patient behavior.

Triple aim

- Improve health outcomes
- Better patient care
- Lower costs

Low Activation scores correlate with 8-21 percent higher health care costs (Fairview Health System study)

Good Rapport = Better patient engagement

Patient interface techniques:

- Smiles from staff-the first and last impression
- No or minimal waiting time
- Apologize for the wait
- Shake hands
- Sit down
- Lean forward
- Eye contact
- Use patient name often
- Crossed legs are good. Crossed arms are bad
- Don't interrupt
- Remember prior life events.
- Final sentences: "Do you have any questions? Did we cover everything?"

Communication skills training – tailored to the literacy level of the patient.

Use patient satisfaction surveys to improve.

How to make the patient feel good about your office

- Make scheduling simple
- Our hours are often not the best hours for them: 7-8 am, 12-1 pm, 5-6 pm, evenings, weekends

Ask about common symptoms

Dyspepsia

Allergies

Fatigue

Sadness/Depression

Sleep

Improve the perceived length of the office visit and improve your work flow

For depressed patients - they fill out and score a depression scale and read on treatment while you see another patient

For scattered patients – see another patient while they fill out an extensive ROS

The patient list

Specific dates for visits work better than vague time intervals, e.g "See me the last week of August," not "See me in 3-4 months."

50-50 chance of follow up or sending records

Don't ask questions with a possible "No" answer.

Leave patient voicemails with <u>your</u> voice and instructions

Call sick patients in the evening.

Social Media – A must do

Texting – only 29% of us get an A

Patient Portal

Patients using a portal are more likely to be screened and do preventive visits

Make it easy

Increases medication adherence, thus improved health, reduced admits, fewer ER visits

Scheduling

Lab results

Refills

Payments

Education

Messages

Many patient Apps for their smart phones and computers

Social Media not restricted to just the young.

Telemedicine

2 kinds- your patients and new patients

Your patients – on vacation, relocating, "snowbirds", recently discharged patients, wound monitoring

Private office vs Urgent Care vs Hospital fast track ER

Quality of Medical Care
- Measured by how you look and how your office looks
- Best Doctor polls
- Newspaper Editorialist
- Online Reputation
  - Repair bad rep
- TV news and health care reporters

Be Thorough
- Med list
- Allergy List
- Update regularly
- Include herbs and supplements

Depression lecture

Every Single Chart review
- 4 sites: last progress note, last refill, last call, Data Base of problems and meds.

Use the Review of Systems

Complete Physicals - the Key

Use Video/Computer to instruct and educate

Health Promotion Recommendations
- Specialty Specific
- Family Practice
  - IBW
  - Exercise
  - Alcohol
  - Smoking
  - Drugs
  - Herbs/Supplements
  - Sleep
- Depression
- DWI
- Skin
- Sunscreen
- Stress
- Fruits/Vegetables
- Fat grams
- Cholesterol
- Bakery items
- BBQ
- Caffeine
- Cancer
- Family History
- Self Exams
- Complete Physical

Colon screening
Stress tests
Allergies
Pap
Contraception
HRT
ED
Bone Density scans
CT's
Calcium/Vit D
Aspirin
Folic acid
Vaccines for kids
Flu shot
‘ Hep B
Pneumonia vaccine
Meningitis vaccine
Teenagers
STD
Guidelines
Miscellaneous

Preventive Care List in poster form for the rooms

Brochure – Use it wisely

Patient Centered Medical Home – "one stop shopping"

Advertising
Magnets for the refrigerator
Win-Win "sales" - At towel dispensers, on the walls, waiting room easel, email

Cost of care affects patient engagement

High Deductible plan issues

On line procedure estimator rather than a price list

Concierge medicine

Patient Literacy
Assess the medical IQ and general IQ
Tailor leaflets, brochures, handouts to the education level, age, language

Bibliotherapy
Under used and valuable
Paper and digital

Shared Decision Making

Study result: Patients who receive enhanced decision making support ultimately had overall medical costs that were 5.3 percent lower than those receiving usual support and there were 12.5 percent fewer admissions to the hospital

SELF EVALUATION

## Facilitating Patient Engagement for Better Care

**True/False**

**1.** Patient Activation has been shown to improve medication adherence and reduce hospital admissions.

**2.** Social media is not a very effective way to improve patient engagement.

**3.** The use of a patient portal reduces the use of emergency room services.

**4.** There are no good websites to help patients with shared decision making.

**5.** Social media use is becoming more common in older individuals and low income individuals.

**6.** It is acceptable for a physician to ask a patient to post a comment on internet sites that evaluate physicians.

**7.** For patients with multiple symptoms, asking them to rank the top 5 symptoms is helpful to get them focused.

**8.** Patients who use enhanced decision making have overall lower medical costs than those not using this health aid.

**ANSWER KEY:** 1. T, 2. F, 3. T, 4. F, 5. T, 6. T, 7. T, 8. T